MINUTES OF 334TH MEETING OF REGISTRATION BOARD HELD ON 25TH JANUARY, 2024

DRUG REGULATORY AUTHORITY OF PAKISTAN
T.F. COMPLEX, MAUVE AREA, G-9/4
ISLAMABAD.

334th meeting of Registration Board was held on 25th January, 2024 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad.

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

Following members attended the meeting:

1.	Lt. Gen.(R) Prof. Dr. Karamat A. Karmat, (HI-M, SI-M), Former Surgeon General Pakistan, Rawalpindi (On line)	Co-opted Member
2.	Mr. Ahmad Din Ansari, Director, Division of BE&R	Member
3.	Ch. Ch. Zeeshan Nazir Bajar, Additional Director	Secretary
4.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law & Justice, Islamabad.	Member
5.	Mr. Ghulam Mujtaba, Deputy Director, Rep. of IPO, Islamabad.	Member
6.	Dr. Imranullah Khan, Senior Drug Analyst. Rep of Director DTL, Govt. of KP	Member
7.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan Quetta	Member
8.	Mr. Iftikhar A. Chaudhary, Hospital Pharmacist, Lahore	Co-opted Member
9.	Dr. Muhammad Akram, Animal Husbandry Commissioner	Co-opted Member
10.	Ms. Mehwish Tanveer, Assistant Director. Rep. of Division of QA&LT	Member
11.	Dr. Qurban Ali, Ex-Director General, NVL, Veterinary Expert	Co-opted Member
12.	Dr. Ghayour Ahmed, Assistant Director, Rep. of Director, MD&MC Division	Member

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

Item No. I. Confirmation of Minutes of 333rd meeting of Registration Board

333rd meeting of Registration Board was held on 19th & 20th December, 2023. Accordingly, draft minutes of the 333rd meeting of Registration Board were prepared and circulated among the members through email on 9th January, 2024 for their perusal / approval / comments (if any) by 13th January, 2024. (9:00 am). No member commented on the draft minutes. Hence minutes of 333rd meeting of the Registration Board stand approved. Accordingly, fair minutes of 333rd meeting were signed and sent to relevant Division for compliance / implementation of decision of Board.

Decision: Registration Board noted the information and unanimously confirmed minutes of 333rd meeting of Registration Board.

Item No. II Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title	Case no.
1.	Ms. Najia Saleem	Evaluator PEC-X	1 – 119
2.	Mr. Salateen Waseem Philip	Deputy Director (PE&R)	120 – 135

Agenda of Evaluator PEC-X

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

a. New Routine Cases

1.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Endo-Try Plus Oral drench
	Composition	Each ml contains: Febendazole…50mg Triclabendazole…50mg Ivermectin…1mg
	Diary No. Date of R& I & fee	Dy.No 20761 dated 22-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 9869141472)
	Pharmacological Group	Anthelmintic/dewormer
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Trivermall Drench of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 046635)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, sheep, goat, horses, cats and dogs, fish, rabbits, seals **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit the following before issuance of registration letter. • **Fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
2.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Nicox Drench
	Composition	Each ml contains: Niclosamide…75mg Oxibendazole…10mg

	Diary No. Date of R& I & fee	Dy. No 19831 dated 06-07-2022 Rs.30,000/- dated 22-06-2022 (slip No. 28340797527)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Nicsomall Drench of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 046634)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid (General) (Veterinary) section** confirmed vide Letter No. F.1-25/2015-Lic dated 29-08-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
3.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Triver Drench
	Composition	Each ml contains: Triclabendazole…120mg Ivermectin…2mg Albendazole…100mg
	Diary No. Date of R& I & fee	Dy. No 19832 dated 06-07-2022 Rs.30,000/- dated 22-06-2022 (slip No. 76979237676)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml: Decontrolled
	Me-too status	Thunder Drench of M/s Star Laboratories (Pvt) Ltd, Lahore. (Reg. No.058941)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid (General) (Veterinary) section** confirmed vide Letter No. F.1-25/2015-Lic dated 29-08-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
4.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Zurotil Oral Liquid
	Composition	Each ml contains: Toltrazuril…25mg Vitamin A…2.5mg Vitamin K…5mg
	Diary No. Date of R& I & fee	Dy.No 19827 dated 06-07-2022 Rs.30,000/- dated 22-06-2022 (slip No. 7267697142)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications

	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Bio-Toltra Plus Oral Liquid of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 078232)
	GMP status	
	Remarks of the Evaluator [x]	**Oral Liquid (General) (Veterinary) section** confirmed vide Letter No. F.1-25/2015-Lic dated 29-08-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
5.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	TT-100 Premix
	Composition	Each gram contains: Tylosin Tartrate…1000mg
	Diary No. Date of R& I & fee	Dy.No 19828 dated 06-07-2022 Rs.30,000/- dated 22-06-2022 (slip No. 131116004)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	500gm, 1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Tylocon Feed Premix of M/s Lexicon Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 044956)
	GMP status	
	Remarks of the Evaluator [x]	**Oral Powder (General Antibiotic) (Veterinary) section** confirmed vide Letter No. F.1-25/2015-Lic dated 29-08-2018. **Target species:** Calves, goats, sheep, Poultry **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The reference formulation is **Each gram contains:** **Tylosin as Tartrate…1000mg** The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved with BP specifications following label claim: **Each gram contains:** **Tylosin as Tartrate…1000mg** **Firm shall submit the following before issuance of registration letter.** • **Fee Rs. 30,000/- for correction in formulation (salt form) and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
6.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplatyl-20 Premix

	Composition	Each gram contains: Tylosin as Tartrate…200mg
	Diary No. Date of R& I & fee	Dy.No 19829 dated 06-07-2022 Rs.30,000/- dated 22-06-2022 (slip No. 8811747972)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	500gm, 1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Tylofed Feed Premix of M/s Lexicon Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 044957)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Powder (General Antibiotic) (Veterinary) section** confirmed vide Letter No. F.1-25/2015-Lic dated 29-08-2018. **Target species:** Livestock, Poultry **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved with BP specifications. Firm shall submit the following before issuance of registration letter. • **latest GMP inspection report conducted within the period of last three years.** • **fee Rs. 7500/- for correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
7.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplatyl-10 Premix
	Composition	Each gram contains: Tylosin as Tartrate…100mg
	Diary No. Date of R& I & fee	Dy.No 19830 dated 06-07-2022 Rs.30,000/- dated 22-06-2022 (slip No. 351476635819)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	500gm, 1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Tylo-Vet Granules Premix of M/s Medi-Vet (Pvt) Limited, Lahore (Reg. No. 084844)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Powder (General Antibiotic) (Veterinary) section** confirmed vide Letter No. F.1-25/2015-Lic dated 29-08-2018. **Target species:** Livestock, Poultry **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The reference formulation is **Each gram contains:** **Tylosin as Tartrate…100mg**

		The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved with following label claim: **Each gram contains:** **Tylosin as Tartrate…100mg** **Firm shall submit the following before issuance of registration letter.** • **fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
8.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Oxyket L.A Injection 10ml
	Composition	Each ml contains: Oxytetracycline as HCl…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 20537 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 76930089)
	Pharmacological Group	Antibiotic/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Oxyfen LA Injection of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [x]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • **Target species:** Honeybees, livestock, cattle, poultry, fish
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
9.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Iver Vit Injection 10ml
	Composition	Each ml contains: Ivermectin…10mg Vitamin A…25,000 IU Vitamin D3…3,750 IU Vitamin E…25mg
	Diary No. Date of R& I & fee	Dy.No 20539 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 9283819222)
	Pharmacological Group	Anthelmintics/ nutritional supplements
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Bovimec Injection (10ml, 100ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No.046563)

	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [x]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • **Target species:** Cattle **Shortcomings:** Conversion of Vitamin A and Vitamin D3 from IU to mg
	Decision: Approved. Firm shall submit conversion of Vitamin A and Vitamin D3 from IU to mg before issuance of registration letter	
10.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Iver Vit Injection 100ml
	Composition	Each ml contains: Ivermectin…10mg Vitamin A…25,000 IU Vitamin D3…3,750 IU Vitamin E…25mg
	Diary No. Date of R& I & fee	Dy.No 20540 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 45147889220)
	Pharmacological Group	Anthelmintics/ nutritional supplements
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Bovimec Injection (10ml, 100ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No.046563)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [x]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • **Target species:** Cattle **Shortcomings:** Conversion of Vitamin A and Vitamin D3 from IU to mg
	Decision: Approved. Firm shall submit conversion of Vitamin A and Vitamin D3 from IU to mg before issuance of registration letter.	
11.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bio-Meloxi Forte Injection 50ml
	Composition	Each ml contains: Meloxicam…200mg
	Diary No. Date of R& I & fee	Dy.No 20538 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 579064572253)
	Pharmacological Group	NSAIDS
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [x]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • **Target species:** Cattle, horses, dogs **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee.	
12.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vita Plus injection 100ml
	Composition	Each ml contains: Vitamin A…5,000,000 IU Vitamin E…2,000 IU Vitamin B6…0.06gm Nicotinamide…0.06gm Vitamin D3…2500,000 IU Vitamin B1…0.2gm Vitamin B12…0.4mg
	Diary No. Date of R& I & fee	Dy.No 20543 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 4023336921)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [x]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Clarification regarding applied formulation is required since Vitamin B12…0.4**mg**/ml is mentioned in label claim on form-5 and throughout the dossier while Vitamin B12…0.4**g**/ml is mentioned on cover letter; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Conversion of Vitamin A, Vitamin E and Vitamin D3 from IU to mg
	Decision: Deferred for following: • **Clarification regarding applied formulation**	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee.** • **Conversion of Vitamin A, Vitamin E and Vitamin D3 from IU to mg**	
13.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vita Plus injection 50ml
	Composition	Each ml contains: Vitamin A…5,000,000 IU Vitamin E…2,000 IU Vitamin B6…0.06gm Nicotinamide…0.06gm Vitamin D3…2500,000 IU Vitamin B1…0.2gm Vitamin B12…0.4mg
	Diary No. Date of R& I & fee	Dy.No 20543 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 320797430)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [x]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Conversion of Vitamin A, Vitamin E and Vitamin D3 from IU to mg
	Decision: Deferred for following: • **Clarification regarding applied formulation** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee.** • **Conversion of Vitamin A, Vitamin E and Vitamin D3 from IU to mg**	
14.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vita Plus injection 20ml
	Composition	Each ml contains: Vitamin A…5,000,000 IU Vitamin E…2,000 IU Vitamin B6…0.06gm Nicotinamide…0.06gm Vitamin D3…2500,000 IU Vitamin B1…0.2gm Vitamin B12…0.4mg

	Diary No. Date of R& I & fee	Dy.No 20541 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 001502286136)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Clarification regarding applied formulation is required since Vitamin B12…0.4**mg**/ml is mentioned in label claim on form-5 and throughout the dossier while Vitamin B12…0.4**g**/ml is mentioned on cover letter; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Conversion of Vitamin A, Vitamin E and Vitamin D3 from IU to mg
	Decision: Deferred for following: • **Clarification regarding applied formulation** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee.** • **Conversion of Vitamin A, Vitamin E and Vitamin D3 from IU to mg**	
15.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Doramall 1% Injection 10ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 19515 dated 04-07-2022 Rs.30,000/- dated 23-06-2022 (slip No. 68391826)
	Pharmacological Group	Anthelminthic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Dectomax Injectable Solution (10ml, 50ml) of M/s Ghazi Brothers, Karachi (Reg. No. 027479)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Cattle and sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit the following before issuance of registration letter.	

	• **Fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
16.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Doramall 1% Injection 50ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 19516 dated 04-07-2022 Rs.30,000/- dated 23-06-2022 (slip No. 616855365609)
	Pharmacological Group	Anthelminthic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Dectomax Injectable Solution (10ml, 50ml) of M/s Ghazi Brothers, Karachi (Reg. No. 027479)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Cattle and sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit the following before issuance of registration letter. • **Fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
17.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Ivermall 3.15% Injection 50ml
	Composition	Each ml contains: Ivermectin…31.5mg
	Diary No. Date of R& I & fee	Dy.No 19514 dated 04-07-2022 Rs.30,000/- dated 23-06-2022 (slip No. 1554742314)
	Pharmacological Group	Anthelminthic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Elvomec Star Injection 3.15% (50ml) of M/s Elko Organization (Pvt) Ltd., Karachi. (Reg. No. 063728)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Cattle, camels, sheep and goats **Shortcomings:**

		• Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
18.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	AR TNF Super Plus Powder
	Composition	Each gram contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 19517 dated 04-07-2022 Rs.30,000/- dated 23-06-2022 (slip No. 327958186)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	E-Col Water Soluble Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 081733)
	GMP status	
	Remarks of the Evaluator [X]	**Powder (General) Section** confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007 **Target species:** Calves, goats, sheep, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit the following before issuance of registration letter. • **Fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Latest GMP inspection report conducted within the period of last three years.**	
19.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Fen Injection 100ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 19925 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 3428744475)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021

		M/s SB pharma: GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Dogs, cats, horses, small animals, other large animals, birds, exotic animals **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
20.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Fen Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 19924 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 61279267300)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Dogs, cats, horses, small animals, other large animals, birds, exotic animals **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.

	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
21.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Moxin Injection 50ml
	Composition	Each ml contains: Amoxycillin (as Trihydrate)…150mg
	Diary No. Date of R& I & fee	Dy.No 19923 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 1521142657)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Novamox LA Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043135)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, sheep, dogs, cats, horses, poultry **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
22.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Moxin Injection 100ml
	Composition	Each ml contains: Amoxycillin (as Trihydrate)…150mg
	Diary No. Date of R& I & fee	Dy.No 19926 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 178516704684)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Novamox LA Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043135)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, sheep, dogs, cats, horses, poultry **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
23.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Trim Injection 50ml
	Composition	Each ml contains: Sulfadiazine…400mg Trimethoprim…80mg
	Diary No. Date of R& I & fee	Dy.No 19927 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 119394599)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Sulbectra Injection (50ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 088121)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, buffaloes, sheep, goats, horses

		Shortcomings: • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
24.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Mycin injection 50ml
	Composition	Each ml contains: Benzathine Penicillin G…100,000IU Procaine Penicillin G…150,000IU Dihydrostreptomycin Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 19922 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 348991511)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Probenzacin Injection (50ml) of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 088838)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
25.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Enrocin 10% Injection 100ml
	Composition	Each ml contains: Enrofloxacin …100mg

	Diary No. Date of R& I & fee	Dy.No 19921 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 996640972)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Enro-Pro 10 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113561)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, buffaloes, sheep, goats, poultry **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
26.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Cam Injection 100ml
	Composition	Each ml contains: Meloxicam…7.5mg
	Diary No. Date of R& I & fee	Dy.No 19920 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 8281418166)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Exikam Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 109937)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:**

		• Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
27.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SBTylo Plus 20% Injection 100ml
	Composition	Each ml contains: Tylosin Tartrate eq. to Tylosin base…200mg
	Diary No. Date of R& I & fee	Dy.No 19919 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 759593590514)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Tylox-20 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113562)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, buffaloes, sheep, goats, dogs, poultry **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
28.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB OXY Forte Injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl eq. to Ocytetracycline …200mg

	Diary No. Date of R& I & fee	Dy.No 19930 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 7933705581)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Levamycin-20% Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113401)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, horses, sheep, goats, cats, dogs **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
29.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB OXY 5% Injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl eq. to Ocytetracycline …50mg
	Diary No. Date of R& I & fee	Dy.No 19918 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 8733707161)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Onyx 50 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113555)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, horses, sheep, goats, cats, dogs

		Shortcomings: • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
30.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Mectin Injection 50ml
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 19928 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 089395219176)
	Pharmacological Group	Anthelminthic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, buffaloes, camels, sheep, goats **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify. • Clarification regarding applied formulation is required since Ivermectin…10mg **per ml** is mentioned in label claim on form-5 and throughout the dossier while Ivermectin…10mg **per 100ml** is mentioned on cover letter; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP** • **Clarification regarding applied formulation and accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

31.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Mectin Pro Injection 50ml
	Composition	Each ml contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 19929 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 75687228)
	Pharmacological Group	Anthelminthic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [x]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Cattle, buffaloes, camels, sheep, goats **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify. • Clarification regarding applied formulation is required since Ivermectin…10mg and Clorsulon…100mg **per ml** is mentioned in label claim on form-5 and throughout the dossier while Ivermectin…10mg and Clorsulon…100mg **per 100ml** is mentioned on cover letter; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP** • **Clarification regarding applied formulation and accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
32.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paractin Super Injection 10ml
	Composition	Each ml contains: Ivermectin…10mg Clorsulon…100mg

	Diary No. Date of R& I & fee	Dy.No 19947 dated 07-07-2022 Rs.30,000/- dated 09-06-2022 (slip No. 3850650101)
	Pharmacological Group	Anthelminthic/ anti-parasitic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Clortin Injection (10ml) of M/s Univet Pharmaceuticals, Rawalpindi (Reg. No. 113567)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [x]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014.
	Decision: Approved.	
33.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paractin Super Injection 100ml
	Composition	Each ml contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 19949 dated 07-07-2022 Rs.30,000/- dated 09-06-2022 (slip No. 444939119)
	Pharmacological Group	Anthelminthic/ anti-parasitic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Clortin Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi (Reg. No. 113570)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [x]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014.
	Decision: Approved.	
34.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paractin Super Injection 50ml
	Composition	Each ml contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 19948 dated 07-07-2022 Rs.30,000/- dated 09-06-2022 (slip No. 2459635495)
	Pharmacological Group	Anthelminthic/ anti-parasitic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Clortin Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi (Reg. No. 113569)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [x]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014.
	Decision: Approved.	

35.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection 10ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 19941 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 6011027756)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.043141)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, dairy bulls
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
36.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 19942 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 1077717717)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.043141)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, dairy bulls
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
37.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection 100ml

	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 19943 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 97238058)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.043141)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, dairy bulls
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
38.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Furosefar Injection 50ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 19939 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 5212544938)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Frusicon Injection (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No.049685)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Dogs, horses
	Decision: Approved.	
39.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Furosefar Injection 100ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 19940 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 10161159352)
	Pharmacological Group	Diuretic
	Type of Form	Form 5

	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Frusicon Injection (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No.049685)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Dogs, horses
	Decision: Approved.	
40.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Furosefar Injection 10ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 19938 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 1531929274)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Frusicon Injection (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No.049685)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Dogs, horses
	Decision: Approved.	
41.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Butafar Injection 50ml
	Composition	Each ml contains: **Phenylbutazone** …200mg
	Diary No. Date of R& I & fee	Dy.No 19934 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 9352701106)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Vutazon SS Injectable Solution (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 048280)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.

	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horses and ponies
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
42.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Butafar Injection 100ml
	Composition	Each ml contains: **Phenylbutazone** …200mg
	Diary No. Date of R& I & fee	Dy.No 19935 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 50316143217)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Vutazon SS Injectable Solution (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 048280)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horses and ponies
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
43.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Bromofar Injection 10ml
	Composition	Each ml contains: Enrofloxacin…100mg Bromhexine HCl... 5mg
	Diary No. Date of R& I & fee	Dy.No 19944 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 23749520520)
	Pharmacological Group	Antibacterial/ mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Bromoflox Injection (10ml, 20ml, 50ml, 100ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 075603)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffaloes, horses, sheep, goats, dogs, poultry

	Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
44.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Bromofar Injection 50ml
	Composition	Each ml contains: Enrofloxacin…100mg Bromhexine HCl... 5mg
	Diary No. Date of R& I & fee	Dy.No 19945 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 891174832217)
	Pharmacological Group	Antibacterial/ mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Bromoflox Injection (10ml, 20ml, 50ml, 100ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 075603)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffaloes, horses, sheep, goats, dogs, poultry
	Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
45.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Bromofar Injection 100ml
	Composition	Each ml contains: Enrofloxacin…100mg Bromhexine HCl... 5mg
	Diary No. Date of R& I & fee	Dy.No 19946 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 8837301756)
	Pharmacological Group	Antibacterial/ mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Bromoflox Injection (10ml, 20ml, 50ml, 100ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 075603)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffaloes, horses, sheep, goats, dogs, poultry
	Decision: Approved. The firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	

46.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Mycofar 30 Injection 10ml
	Composition	Each ml contains: Tilmicosin…300mg
	Diary No. Date of R& I & fee	Dy.No 19936 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 55607463315)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Tilcolina Injection (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 049674)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved with following label claim; **Each ml contains:** **Tilmicosin as Phosphate…300mg** **The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
47.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Mycofar 30 Injection 100ml
	Composition	Each ml contains: Tilmicosin…300mg
	Diary No. Date of R& I & fee	Dy.No 19937 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 5229438024)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Tilcolina Injection (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 049674)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep **Shortcomings:**

		• The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved with following label claim; **Each ml contains:** **Tilmicosin as Phosphate…300mg** **The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
48.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Florofar Injection 100ml
	Composition	Each ml contains: Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 19933 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 0562591336)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Phenacol Injection (100ml) of M/s Manhattan Pharma Karachi (Reg. No. 057040)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014.
	Decision: Approved. The firm shall submit fee Rs. 7,500/- for correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
49.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Triozin oral suspension
	Composition	Each ml contains: Trimethoprim …80mg Sulphadiazine …400mg
	Diary No. Date of R& I & fee	Dy.No 19932 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 01530012494)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 500ml, 1000ml; Decontrolled
	Me-too status	Tribactral Forte Suspension of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 029607)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary oral Liquid (General)** section confirmed vide panel inspection report dated 02-07-2021 for renewal of DML **Target species:** Horse, camel, sheep, goat, poultry
	Decision: Approved.	

50.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Sonvit -600 Powder
	Composition	Each gram contains: Oxytetracycline HCl…250mg Neomycin Sulphate…100mg Sodium Sulphate…60mg Vitamin A Acetate…2500IU Vitamin D3…500IU Vitamin C…100mg Vitamin E Acetate…1mg
	Diary No. Date of R& I & fee	Dy.No 19931 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 29956040272)
	Pharmacological Group	Antibiotic/vitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm; Decontrolled
	Me-too status	**Could not be confirmed in the applied combination**
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Powder (General)** section confirmed vide panel inspection report dated 02-07-2021 for renewal of DML **Target species:** Poultry **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee.	

Case no. 02 Registration applications of newly granted DML (Veterinary)

a. New cases (New DML)

I. M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10A and 29/B, Small Industrial Estate, Bhimber, AJK.

CLB in its 290th meeting held on 28th April, 2023 has considered and approved the grant of DML by way of formulation with following sections:

A. Oral Powder Section-I Vet. (General)
B. Oral Powder Section-II Vet. (General)
C. Liquid Spray Section Vet. (General)
D. Liquid Section-I Vet. (General)
E. Liquid Section-II Vet. (General)
F. Liquid Injection Section Vet. (General)
G. Liquid Injectable Section Vet. (Steroid)
H. Liquid Injectable Penicillin (Veterinary)
I. Dry Powder Injectable Penicillin (Veterinary)
J. Bulk Powder Penicillin Section (Vet.)

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

Section	Already considered in M-331		Balance molecules	No. of applied Products	No. of applied Molecules
	No. of molecules	No. of products			
Liquid Injectable Section Vet. (Steroid)	-	-	-	24	09
Oral Powder Section-I Vet. (General)	-	-	-	22	10
Liquid Injectable Penicillin (Veterinary) Section	09	36	01	01	01

Liquid Injectable Section Vet. (Steroid)
(09 Molecules/ 24 products)

51.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Fluoron Injection 50ml
	Composition	Each 100ml contains: **9 Alpha Fluoro Prednisolone** …… 0.2 gm
	Diary No. Date of R& I & fee	Dy. No. 23257 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 57804401724)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Abicorten Injectable solution (50ml) of M/s Prix Pharma (Reg. No. 020756)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
52.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Fluoron Injection 10ml
	Composition	Each ml contains: **9 Alpha Fluoro Prednisolone** …… 0.2 gm
	Diary No. Date of R& I & fee	Dy. No. 23256 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 12645908129)
	Pharmacological Group	Steroid
	Type of Form	Form 5

	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	I-Alpha Pre-Injection (10ml) of M/s International Pharma Labs (Reg. No. 099032)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
53.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predef Injection 10ml
	Composition	Each ml contains: Isoflupredon Acetate …… 2 mg
	Diary No. Date of R& I & fee	Dy. No. 23252 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 025714366)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Isodon Injection (10ml) of M/s. Grand Pharma (Reg. No. 111542)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Approved.	
54.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predef Injection 50ml
	Composition	Each ml contains: Isoflupredon Acetate …… 2 mg
	Diary No. Date of R& I & fee	Dy. No. 23253 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 2861939115)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Isopred Suspension Injection (50ml) of M/s. Alina Combine Pharmaceutical Karachi. (Reg. No. 063701)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Approved.	
55.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tysone Injection 20ml
	Composition	Each ml contains: Thiamphenicol …… 200mg

		Tylosin Tartrate …… 57.5mg **Prednisolone as Acetate** …… 5mg
	Diary No. Date of R& I & fee	Dy. No. 23254 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 776389840268)
	Pharmacological Group	Steroid / Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	20ml, Decontrolled
	Me-too status	Tylopen Injection (20ml, 50ml) of M/s Selmore agencies Pvt. Ltd. Lahore (Reg. No. 058815)
	GMP status	New DML
	Remarks of the Evaluator [x]	**Target species:** Cattle, goat, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
56.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tysone Injection 50ml
	Composition	Each ml contains: Thiamphenicol …… 200mg Tylosin Tartrate …… 57.5mg **Prednisolone as Acetate** …… 5mg
	Diary No. Date of R& I & fee	Dy. No. 23255 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 28822510335)
	Pharmacological Group	Steroid / Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Tylopen Injection (20ml, 50ml) of M/s Selmore agencies Pvt. Ltd. Lahore (Reg. No. 058815)
	GMP status	New DML
	Remarks of the Evaluator [x]	**Target species:** Cattle, goat, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
57.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Dexazon 1 Injection 50ml
	Composition	Each ml contains: **Dexamethasone (as sodium phosphate)** … 1mg
	Diary No. Date of R& I & fee	Dy. No. 23237 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 6831285510)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml, Decontrolled

	Me-too status	Dexamethasone 1mg/ml Injection (50ml) of M/s. Venus Pharma (Reg. No. 031511)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
58.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Dexazon 2 Injection 50ml
	Composition	Each ml contains: **Dexamethasone (as sodium phosphate)** … 2mg
	Diary No. Date of R& I & fee	Dy. No. 23238 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 162276861)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Dexamethasone Injection (50ml) of M/s. Elko Organization Karachi (Reg. No. 017071)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
59.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Injection 10ml
	Composition	Each ml contains: **Prednisolone Acetate** …..... 5 mg Tylosin Tartrate ..... 100 mg Oxytetracycline HCl …..... 50 mg
	Diary No. Date of R& I & fee	Dy. No. 23247 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 44785727989)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Top-Vet Injection of M/s Breeze Pharma Islamabad (Reg. No. 059180)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Horse, cattle, sheep, goat, dog, cat
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
60.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Injection 50ml

	Composition	Each ml contains: **Prednisolone Acetate** …..... 5 mg Tylosin Tartrate ..... 100 mg Oxytetracycline HCl …..... 50 mg
	Diary No. Date of R& I & fee	Dy. No. 23248 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 824953892)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Top-Vet Injection of M/s Breeze Pharma Islamabad (Reg. No. 059180)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Horse, cattle, sheep, goat, dog, cat
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
61.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Forte Injection 10ml
	Composition	Each ml contains: **Prednisolone Acetate** …..... 7.50mg Tylosin Tartrate ..... 100mg Oxytetracycline HCl..... 50gm
	Diary No. Date of R& I & fee	Dy. No. 23249 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 718745543161)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Tylox-P Injection of M/s. Breeze Pharma (Reg. No. 063789)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Horse, cattle, sheep, goat, dog, cat
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
62.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Forte Injection 50ml
	Composition	Each ml contains: **Prednisolone Acetate** …..... 7.50mg Tylosin Tartrate ..... 100mg Oxytetracycline HCl..... 50gm
	Diary No. Date of R& I & fee	Dy. No. 23250 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 39998905948)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5

	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Tylox-P Injection of M/s. Breeze Pharma (Reg. No. 063789)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Horse, cattle, sheep, goat, dog, cat
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
63.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Forte Injection 100ml
	Composition	Each ml contains: **Prednisolone Acetate** …..... 7.50mg Tylosin Tartrate ..... 100mg Oxytetracycline HCl..... 50gm
	Diary No. Date of R& I & fee	Dy. No. 23251 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 695964687182)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Tylox-P Injection of M/s. Breeze Pharma (Reg. No. 063789)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Horse, cattle, sheep, goat, dog, cat
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
64.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predmin Injection 10ml
	Composition	Each ml contains: **Prednisolone** …… 10mg Chlorpheniramine Maleate ….. 4mg
	Diary No. Date of R& I & fee	Dy. No. 23241 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 868560927301)
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Solomin Injection of M/s. Selmore Pharmaceuticals (Reg. No. 049642)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	

65.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predmin Injection 50ml
	Composition	Each ml contains: **Prednisolone** …… 10mg Chlorpheniramine Maleate ….. 4mg
	Diary No. Date of R& I & fee	Dy. No. 23242 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 63785834)
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Solomin Injection of M/s. Selmore Pharmaceuticals (Reg. No. 049642)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
66.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsone Injection 10ml
	Composition	Each ml contains: **Prednisolone (as acetate)** …… 7.5mg **Dexamethasone (as sodium phosphate)** ... 2.5mg
	Diary No. Date of R& I & fee	Dy. No. 23239 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 8069319710)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Penacort Injection Selmore Pharmaceuticals (Reg. No. 029665)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, horse, sheep, goat, calves, foals, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
67.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsone Injection 50ml
	Composition	Each ml contains: **Prednisolone (as acetate)** …… 7.5mg **Dexamethasone (as sodium phosphate)** ... 2.5mg
	Diary No. Date of R& I & fee	Dy. No. 23240 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 84054518230)
	Pharmacological Group	Steroid
	Type of Form	Form 5

	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Penacort Injection Selmore Pharmaceuticals (Reg. No. 029665)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, horse, sheep, goat, calves, foals, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
68.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsol-25 Injection 10ml
	Composition	Each ml contains: **Prednisolone acetate** …… 25mg
	Diary No. Date of R& I & fee	Dy. No. 23233 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 61942942187)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Predison Injection 2.5% of M/s. Manhattan Pharma (Reg. No. 035091)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
69.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsol-25 Injection 50ml
	Composition	Each ml contains: **Prednisolone acetate** …… 25mg
	Diary No. Date of R& I & fee	Dy. No. 23234 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 7233 161)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Predison Injection 2.5% of M/s. Manhattan Pharma (Reg. No. 035091)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
70.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	Predsol-10 Injection 10ml
	Composition	Each ml contains: **Prednisolone acetate** …… 10mg
	Diary No. Date of R& I & fee	Dy. No. 23235 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 1602696860)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	GP-Pred Injection (10ml) of M/s. Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 111541)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
71.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsol-10 Injection 50ml
	Composition	Each ml contains: **Prednisolone acetate** …… 10mg
	Diary No. Date of R& I & fee	Dy. No. 23236 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 97933535087)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Premsone 10 Injection (50ml) of M/s. Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111333)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
72.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Genta Combizon Injection 10ml
	Composition	Each ml contains: Tylosin Tartrate ……. 150mg Gentamycin Sulphate ……..…… 60mg **Dexamethasone as Sodium Phosphate** … 0.265mg Chlorpheniramine (Maleate) … 7.5mg
	Diary No. Date of R& I & fee	Dy. No. 23244 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 52975174803)
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications

	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Genta Combisone Injection of M/s. Leads Pharma (Reg. No. 046696)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
73.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Genta Combizon Injection 50ml
	Composition	Each ml contains: Tylosin Tartrate ……. 150mg Gentamycin Sulphate …….……. 60mg **Dexamethasone as Sodium Phosphate** … 0.265mg Chlorpheniramine (Maleate) … 7.5mg
	Diary No. Date of R& I & fee	Dy. No. 23245 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 30105372808)
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Genta Combisone Injection of M/s. Leads Pharma (Reg. No. 046696)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
74.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Genta Combizon Injection 100ml
	Composition	Each ml contains: Tylosin Tartrate ……. 150mg Gentamycin Sulphate …….……. 60mg **Dexamethasone as Sodium Phosphate** … 0.265mg Chlorpheniramine (Maleate) … 7.5mg
	Diary No. Date of R& I & fee	Dy. No. 23246 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 6391273819)
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Genta Combisone Injection of M/s. Leads Pharma (Reg. No. 046696)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep

	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Liquid Injectable Penicillin (Veterinary) Section (01 Molecule/ 01 Product)		
75.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Biodex Injection 50ml
	Composition	Each ml contains: Benzyl Penicillin Procaine … 125,000IU Benzathine Penicillin G … 125,000IU Dihydrostreptomycin Sulphate … 0.25g **Dexamethasone Sodium Phosphate … 0.20mg** **Dexamethasone-21-Isonicotinate … 0.20mg**
	Diary No. Date of R& I & fee	Dy. No. 23243 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 9946428151)
	Pharmacological Group	Penicillin Antibacterial/ Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	BDEX Liquid Injection of M/s. Selmore Pharmaceuticals (Reg. No. 080952)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Oral Powder Section-I Vet. (General) (10 Molecules/ 22 Products)		
76.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Vimto Powder
	Composition	Each gram contains: Vitamin D3 …… 100 IU Vitamin E …….. 0.125 IU Ferrous Sulphate ……. 1mg Cobalt Sulphate …… 0.010mg Copper Sulphate ……. 0.60mg Potassium Iodide ……. 0.040mg Zinc Sulphate …… 3mg Manganese Sulphate …… 2mg Sodium Selenite …… 0.003mg Sodium Chloride …… 45mg Magnesium Sulphate …… 55mg Calcium Chloride …… 195mg Phosphorus …….. 153mg
	Diary No. Date of R& I & fee	Dy. No. 23326 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 20793390)
	Pharmacological Group	Minerals
	Type of Form	Form 5

	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Vet-Min of M/s. Breeze Pharma (Reg. No. 091885)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
77.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Treat CRD 48 WSP
	Composition	Each gram contains: Doxycycline HCl …… 200mg Tylosin Tartrate …… 100mg Colistin Sulphate …… 0.48 MIU Bromhexine HCl …… 5mg
	Diary No. Date of R& I & fee	Dy. No. 23312 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 729631476362)
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Maxdox Water Soluble Powder of M/s. Baariq Pharmaceuticals (Reg. No. 087144)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
78.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Treat CRD 50 WSP
	Composition	Each gram contains: Doxycycline HCl …… 200mg Tylosin Tartrate …… 100mg Colistin Sulphate …… 0.050MIU Bromhexine HCl …… 2mg
	Diary No. Date of R& I & fee	Dy. No. 23311 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 52106062524)
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Respicure Water Soluble Powder of Baariq Pharmaceuticals (Reg. No. 087141)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry

	Decision: Approved.	
79.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Treat CRD 72 WSP
	Composition	Each gram contains: Doxycycline HCl …… 400mg Tylosin Tartrate …… 200mg Colistin Sulphate …… 100mg Bromhexine HCl …… 20mg
	Diary No. Date of R& I & fee	Dy. No. 23310 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 656510136)
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Multidox Oral Powder of M/s. Hawk Bio Pharma (Reg. No. 078395)
	GMP status	New DML
	Remarks of the Evaluator [x]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
80.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Treat CRD 68 WSP
	Composition	Each gram contains: Doxycycline HCl …… 400mg Tylosin Tartrate …… 200mg Colistin Sulphate …… 60mg Bromhexine HCl …… 20mg
	Diary No. Date of R& I & fee	Dy. No. 23309 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 8060392831)
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Anti-Bios W/S Powder of Baariq Pharmaceuticals (Reg. No. 087143)
	GMP status	New DML
	Remarks of the Evaluator [x]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
81.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Treat CRD 66 WSP
	Composition	Each gram contains:

		Doxycycline HCl …… 400mg Tylosin Tartrate …… 200mg Colistin Sulphate …… 0.5MIU Bromhexine HCl …… 10mg
	Diary No. Date of R& I & fee	Dy. No. 23308 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 3701884486)
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Broxtin 24-Powder of M/s. Leads Pharma (Reg. No. 088045)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
82.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Treat CRD 43 WSP
	Composition	Each gram contains: Tylosin Tartrate…… 100mg Doxycycline……. 200mg Bromhexine HCl…….. 100mg Colistin Sulphate ……. 30mg
	Diary No. Date of R& I & fee	Dy. No. 23307 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 060996566)
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Biosin TD Powder of Leads Pharma Islamabad (Reg. No. 044951)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
83.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Parazon WSP
	Composition	Each gram contains: **Paracetamol** …… 200mg Vitamin C …… 50mg Potassium Carbonate … 125mg Sodium Bicarbonate … 125mg Vitamin E …… 125mg

	Diary No. Date of R& I & fee	Dy. No. 23306 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 794705221568)
	Pharmacological Group	Analgesic, Antipyretic, Antioxidant, Electrolyte, Vitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Parascorbic Powder of Baariq Pharmaceuticals (Reg. No. 087140)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
84.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ncozon 24 WSP
	Composition	Each gram contains: Oxytetracycline HCl …… 200mg Neomycin Sulphate …… 200mg Colistin Sulphate …… 0.24MIU
	Diary No. Date of R& I & fee	Dy. No. 23315 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 82708761054)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Oxyno Plus Water Soluble Powder of Attabak Pharmaceuticals (Reg. No. 075682)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
85.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ncozon 30 WSP
	Composition	Each gram contains: Oxytetracycline HCl …… 250mg Neomycin Sulphate …… 250mg Colistin Sulphate …… 0.30MIU
	Diary No. Date of R& I & fee	Dy. No. 23316 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 109420272254)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled

	Me-too status	Oxycol Forte Powder of M/s. Attabak Pharmaceuticals (Reg. No. 071068)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
86.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ncozon 50 WSP
	Composition	Each gram contains: Oxytetracycline HCl …… 300gm Neomycin Sulphate …… 250gm Colistin Sulphate …… 500MIU
	Diary No. Date of R& I & fee	Dy. No. 23317 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 2641581984)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	ST Neolistin Powder of M/s. Leads Pharma (Reg. No. 078242)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
87.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ncozon 95 WSP
	Composition	Each gram contains: Oxytetracycline HCl …… 200mg Neomycin Sulphate …… 200mg Colistin Sulphate ……. 0.55MIU
	Diary No. Date of R& I & fee	Dy. No. 23319 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 8148077022)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	N-OX-C Water Soluble Powder by Nawal Pharmaceuticals (Reg. No. 074095)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
88.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ncozon 154 WSP

	Composition	Each gram contains: Oxytetracycline HCl…… 80mg Neomycin Sulphate …… 70mg Colistin Sulphate …… 4mg
	Diary No. Date of R& I & fee	Dy. No. 23318 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 18453445822)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	NOC-154 Oral Powder of Kohinoor Industries (Reg. No. 081307)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
89.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Nefox WSP
	Composition	Each gram contains: Oxytetracycline HCl …… 3mg Neomycin Sulphate …… 1.5mg Florfenicol……1mg
	Diary No. Date of R& I & fee	Dy. No. 23320 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 8933941863)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Ofencin Oral Water Soluble Powder of M/s. D-Maarson Pharmaceuticals (Reg. No. 097869)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, poultry, fish
	Decision: Approved.	
90.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Nefox Extra WSP
	Composition	Each gram contains: Oxytetracycline HCl …… 300mg Neomycin Sulphate …… 150mg Florfenicol……100mg
	Diary No. Date of R& I & fee	Dy. No. 23321 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 5644751580)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5

	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Neoxflor Oral Powder of Baariq Pharmaceuticals (Reg. No. 088638)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, poultry, fish
	Decision: Approved.	
91.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Growth Gold Powder
	Composition	Each gram contains: Vitamin A …….…….. 0.8mm Vitamin D3 ……..….... 0.16mm Vitamin E ……... 0.38mg Vitamin B1 ……..... 1mg Vitamin B2 ……. 1.25mg Vitamin B12 ……... 0.001mg Vitamin B3 …….. 6.25mg Copper Sulphate …….. 0.25mg Magnesium Sulphate … 25mg Calcium Chloride …….. 0.023mg Zinc Sulphate ……. 2.17mg Manganese Sulphate …. 10mg Potassium Iodide …… 0.5mg Sodium Selenite ……. 0.01mg Dicalcium Phosphate (DCP) … 150mg Sodium Chloride ……... 120mg Vitamin B6 …… 4mg
	Diary No. Date of R& I & fee	Dy. No. 23327 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 761800566061)
	Pharmacological Group	Multi Vitamins and Minerals supplements
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	White Gold Powder of M/s. Leads Pharma (Reg. No. 058842)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
92.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Diarrozon WSP
	Composition	Each gram contains: Neomycin Sulphate …… 33.33mg Streptomycin Sulphate …… 33.33mg

		Sulphaguanidine …… 333.33mg Kaolin …… 333.33mg Pectin …… 33.33mg Bismuth Subnitrate …… 166.66mg Vitamin A Acetate …… 2.291mg
	Diary No. Date of R& I & fee	Dy. No. 23313 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 39125521)
	Pharmacological Group	Antibacterial, Anti-Diarrheal, Vitamin
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Dairrolex Water Soluble Powder of M/s. Wimits Pharmaceuticals (Reg. No. 080151)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
93.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Diarrozon Extra WSP
	Composition	Each gram contains: Neomycin Sulphate …… 33.33mg Streptomycin Sulphate …… 33.33mg Sulphaguanidine …… 333.33mg Pectin …… 33.33mg Bismuth Subnitrate …… 166.67mg Vitamin A Acetate …… 6666.67 I.U. Kaolin …… 333.33gm
	Diary No. Date of R& I & fee	Dy. No. 23314 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 4182048245)
	Pharmacological Group	Antibacterial, Anti-Diarrheal, Vitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Diarroban Powder of M/s. Star Labs (Reg. No. 026438)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
94.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Gestzon Powder
	Composition	Each gram contains: Propionic Acid Calcium …… 250mg Propionic Acid Sodium …… 400mg Acetanilide …… 150mg Magnesium Oxide …… 125mg Iron II Sulphate …… 0.4mg

		Zinc Sulphate …… 0.1mg Magnesium Sulphate …… 0.2mg Copper Sulphate ……. 0.45mg Cobalt Sulphate …… 0.4mg Sodium Molybdate …… 0.1mg Sodium Chloride …… 20mg
	Diary No. Date of R& I & fee	Dy. No. 23322 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 17481990)
	Pharmacological Group	Multi-mineral
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	10gm, 50gm, 100gm, 250gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Anigest Powder by M/s My Labs Pharma (Reg. No. 073906)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
95.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Flushzon WSP
	Composition	Each gram contains: Furosemide …… 20mg Sodium Chloride …… 35mg Magnesium Sulphate …… 35mg Manganese Sulphate …… 1mg Calcium Carbonate …… 45mg Potassium Chloride …… 4mg
	Diary No. Date of R& I & fee	Dy. No. 23325 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 91941764080)
	Pharmacological Group	Antibacterial, Diuretic, Electrolyte Replenisher
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Neyphralyte Powder of M/s Selmore Pharma (Reg. No. 071072)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
96.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Fosfit WSP
	Composition	Each gram contains: Calcium Fosfomycin … 200mg Tylosin Tartrate … 50mg Fructose 1,6 Diphosphate …180mg

		Sodium Phosphate … 150mg Magnesium Phosphate … 100mg
	Diary No. Date of R& I & fee	Dy. No. 23323 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 09182495)
	Pharmacological Group	Antibacterial, Electrolyte Replenisher
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626)
	GMP status	New DML
	Remarks of the Evaluator [x]	**Target species:** Calves, goats, sheep, poultry **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
97.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Fosfit Extra WSP
	Composition	Each gram contains: Calcium Fosfomycin … 200mg Tylosin Tartrate … 100mg Fructose 1,6 Diphosphate …180mg Sodium Phosphate … 150mg Magnesium Phosphate … 100mg
	Diary No. Date of R& I & fee	Dy. No. 23324 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 63312945112)
	Pharmacological Group	Antibacterial, Electrolyte Replenisher
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Rold Fos Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109282)
	GMP status	New DML
	Remarks of the Evaluator [x]	**Target species:** Calves, goats, sheep, poultry **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	

b. New cases (New Section)

II. M/s Moreno Iglisias Research Laboratories (Pvt.) Ltd. 21-Km Ferozepur Road, Lahore.

CLB in its 290th meeting held on 28th April, 2023 has considered and approved the grant of following one (01) additional section of the firm M/s **Moreno Iglisias Research Laboratories (Pvt.) Ltd., Lahore** under DML No. 000478 (Formulation).

1. **Liquid Injection Section (General) (Veterinary) (New)**

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

Section	No. of applied Products	No. of applied Molecules
Liquid Injectable Section (General) (Veterinary) New	09	09

Liquid Injectable Section (General) (Veterinary) New
(09 Molecules/ 09 products)

98.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Acemore 2.5% Injection 50ml
	Composition	Each ml contains: **Aceclofenac**…25mg
	Diary No. Date of R& I & fee	Dy. No. 27420 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 475994345360)
	Pharmacological Group	Anti-pyretic/ Analgesic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	I-Acefenac Injection (50ml) of M/s International Pharma Labs. Lahore. (Reg. No. 094437)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Horse, camel, cattle, buffaloes, sheep, goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
99.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Cynomore Injection 50ml
	Composition	Each 2ml Contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy. No. 27422 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 50614849)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Coblavac Injecion (50ml) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 099070)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Horse, calves, foals, cattle, sheep, goats, dogs, cats

	Decision: Approved. Firm shall submit fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
100.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Enromore 10% Injection 100ml
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy. No. 27423 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 09142122043)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml,50ml,100ml, 250ml; Decontrolled
	Me-too status	Enrotil Injectable (100ml) of M/s Selmore Agencies Lahore (Reg. No. 019089)
	GMP status	Additional section
	Remarks of the Evaluator [X]	
	Decision: Approved. Firm shall submit fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
101.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Flu More 5% Injection 100ml
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy. No. 27424 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 1238551920)
	Pharmacological Group	Anti-pyretic/ Analgesic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Floonix Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112246)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Horse, calves, cattle, sheep, goats, dogs, camel **Shortcomings:** • The reference formulation is **Each ml contains:** **Flunixin as Meglumine…50mg** The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved with following label claim. **Each ml contains:** **Flunixin as Meglumine…50mg** **Firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	

102.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Gentamore 10% Injection 100ml
	Composition	Each ml contains: Gentamycin…100mg
	Diary No. Date of R& I & fee	Dy. No. 27425 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 469073172)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Gantasin-10% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112219)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Poultry, horse, cattle, foals and calves, dogs, cats **Shortcomings:** • The reference formulation is **Each ml contains:** **Gentamycin as (Sulfate)…100mg** The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved with following label claim. **Each ml contains:** **Gentamycin as (Sulfate)…100mg** **Firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
103.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Imidomore 12% Injection 100ml
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy. No. 27426 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 556449289873)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml,50ml,100ml, 250ml; Decontrolled
	Me-too status	Durazol Injection (100ml) of M/s Mylab (Pvt) Ltd. Bahawalpur. (Reg. No. 078204)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep, horse, dogs
	Decision: Approved. Firm shall submit fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
104.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.

	Brand Name +Dosage Form + Strength	Ivermore 2% Injection 100ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy. No. 27427 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 4849780899)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml,50ml,100ml, 250ml; Decontrolled
	Me-too status	Vectin 2% Injection (100ml) of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 109907)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Approved. Firm shall submit fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
105.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxymore-F Injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy. No. 27428 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 618658047)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml,50ml,100ml, 250ml; Decontrolled
	Me-too status	OTC Forte LA Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113551)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) and FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
106.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Nitromore 34% Injection 100ml
	Composition	Each ml contains: Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy. No. 27429 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 6318101448)

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml,50ml,100ml, 250ml; Decontrolled
	Me-too status	Troxy-34% Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 034597)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep, goat, buffaloes
	Decision: Approved. Firm shall submit fee Rs. 7500/- for correction in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	

III. M/s Leads Pharma Pvt Ltd. Plot No. 81, Street No. 6, I-10/3, Islamabad

CLB in its 292nd meeting held on 04th October, 2023 has considered and approved the grant of following additional sections of the firm **M/s Leads Pharma Pvt Ltd. Plot No. 81, Street No. 6, I-10/3, Islamabad** under DML No. 000392 (Formulation).

1. **Liquid Injection Vial SVP (Steroid) Vet**
2. **Aerosol (Steroid/Antibiotic) Vet**

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

Section(s)	No. of applied Products	No. of applied Molecules
Liquid Injection Vial SVP (Steroid) Vet	03	03
Aerosol (Steroid/Antibiotic) Vet	07	07

Liquid Injection Vial SVP (Steroid) Vet Section
(03 Molecules/ 03 products)

107.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Prednimin Injection
	Composition	Each ml contains: **Prednisolone Acetate**…10mg Chlorpheniramine Maleate…4mg
	Diary No. Date of R& I & fee	Dy.No 26527 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 10866719)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Not mentioned; Decontrolled
	Me-too status	
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, buffalo, horse, sheep, goat, dog, cat **Shortcomings:** • Clarification regarding applied formulation is required since **Prednisolone Acetate**…10mg/ml is mentioned in label claim on form-5 and throughout the dossier while **Prednisolone as Acetate**…10mg/ml is mentioned in master formula; and provide accordingly evidence of applied formulation/drug

		already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Demanded pack size
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following: • **Clarification regarding applied formulation** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Demanded pack size**	
108.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Lepred Injection
	Composition	Each ml contains: **Isoflupredon Acetate**…2mg
	Diary No. Date of R& I & fee	Dy.No 26520 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No.72616960580)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml; Decontrolled
	Me-too status	Isopred Suspension Injection (**10ml, 25ml, 50ml, 100ml, 500ml**) of M/s Alina Combine Pharmaceutical Karachi. (Reg. No.063701)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, buffalo, horse, small animals **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier • Clarification regarding applied formulation is required since **Isoflupredon Acetate**…2mg/ml is mentioned in label claim on form-5 and throughout the dossier while **Isoflupredon** …2mg /ml is mentioned in master formula; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following: • **Clarification regarding applied formulation** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Choice of only one pack size**	
109.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Solodex Injection

		Each ml Contains:
	Composition	Each ml contains: **Prednisolone Acetate**…7.5mg **Dexamethasone**…2.5mg
	Diary No. Date of R& I & fee	Dy.No 26519 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 77863930)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml; Decontrolled
	Me-too status	Predexa Injection (**10ml, 20ml, 30ml**) of M/s Tarobina Corporation Lahore (Reg. No.020762)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, horse, sheep, goat, dogs, cats **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier • accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status**), in the same pack size/fill volume,** alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Choice of only one pack size**	
Aerosol (Steroid/Antibiotic) Vet Section (07 Molecules/ 07 products)		
110.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Gentox Spray
	Composition	Each ml contains: Oxytetracycline HCl…40mg Gentian-Violet…4mg
	Diary No. Date of R& I & fee	Dy.No 26526 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 5265386496)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	200ml, 300ml; Decontrolled
	Me-too status	Oxyviolet Spray of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088093)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Domestic animals

	Decision: Approved. Firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
111.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Ledogen Spray
	Composition	Each ml contains: Oxytetracycline HCl…40mg Gentian-Violet…4mg Citronella Oil…20mg Permethrin…10mg
	Diary No. Date of R& I & fee	Dy.No 26525 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 9148555386)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	125ml; Decontrolled
	Me-too status	Tetragen-Fly Spray of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088095)
	GMP status	Additional section
	Remarks of the Evaluator [X]	
	Decision: Approved. Firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
112.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Lecort Spray
	Composition	Each ml contains: Oxytetracycline HCl…5mg Hydrocortisone Acetate…1.6mg
	Diary No. Date of R& I & fee	Dy.No 26524 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 845970463824)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	150ml, 250ml; Decontrolled
	Me-too status	Vetasone Aerosol Spray of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.102200)
	GMP status	Additional section
	Remarks of the Evaluator [X]	
	Decision: Approved. Firm shall submit the following before issuance of registration letter; • **fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **evidence of separate dispensing booth for steroidal preparations.**	
113.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Lechlor Spray
	Composition	Each ml contains: Chlortetracycline HCl…15.2mg

	Diary No. Date of R& I & fee	Dy.No 26523 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 922799682324)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	150ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Domestic animals **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee.	
114.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Lecogen Spray
	Composition	Each 60ml contains: **Chloramphenicol**…7.5gm Cetrimide…1.5gm Dimethyl Phthalate…1.5gm Crystal Violet…0.75gm Isopropyl Alcohol…100ml Dimethyl Ether…100ml
	Diary No. Date of R& I & fee	Dy.No 26522 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 6147192385)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
115.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Teraline Spray
	Composition	Each ml contains: Oxytetracycline HCl…35.8mg
	Diary No. Date of R& I & fee	Dy.No 26521 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 8337865842)

	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	150ml, 300ml; Decontrolled
	Me-too status	Iconic-3.5 Spray of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109273)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Domestic animals
	Decision: Approved. Firm shall submit fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
116.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Terasone Spray
	Composition	Each 150ml contains: Oxytetracycline HCl…750mg Hydrocortisone Acetate…240mg
	Diary No. Date of R& I & fee	Dy.No 26518 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 134468178515)
	Pharmacological Group	Antibacterial/ Anti-inflammatory agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	150ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Approved. Firm shall submit the following before issuance of registration letter; • **fee Rs. 7500/- for change in finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **evidence of separate dispensing booth for steroidal preparations.**	

Case no. 03 Registration applications of import cases

a. New Cases (Veterinary)

117.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name and address of marketing authorization holder	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name of exporting country	Korea
	Type of Form	Form-5A

	Diary No. & Date of R& I	Dy.No 12864 Dated 03-05-2021
	Fee including differential fee	Rs: 50,000 Dated 03-05-2021
	Brand Name +Dosage Form + Strength	Prolin Injection
	Composition	Each ml contains: Dinoprost as Dinoprost Tromethamine…5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	10ml, 30ml
	International availability	N/A
	Me-too status	Dprost Liquid Injection (**5mL**) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088647) Heatafas Injection **(50mL**) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 087174)
	Detail of certificates attached	➢ Originally legalized COPP No. M2015798 dated 08-12-2020 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea confirms free sale status of the applied product in country of origin. ➢ Copy of GMP certificate dated 05.11.2019 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea. (Original legalized in **Melen-Pro Oral Powder** dossier) ➢ Copy of letter of authorization (LOA) dated 10-11-2020 to M/s Ghazi Brothers Karachi from PLH for the applied product. (Original legalized in **Melen-Pro Oral Powder** dossier)
	Remarks of the Evaluator [X]	Firm has provided 24-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 10ml and 30ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • 06-month accelerated stability studies data of three batches at zone IV-A conditions.

	Decision: Deferred for following: • **Choice of only one pack size/ fill volume** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **06-month accelerated stability studies data of three batches at zone IV-A conditions.**	
118.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name and address of marketing authorization holder	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name of exporting country	Korea
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12865 Dated 03-05-2021
	Fee including differential fee	Rs: 50,000 Dated 03-05-2021
	Brand Name +Dosage Form + Strength	Quintrol Injection
	Composition	Each ml contains: Fertirelin Acetate…50mcg
	Finished Product Specification	Inhouse
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	4ml, 20ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Originally legalized COPP No. M2015802 dated 08-12-2020 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea confirms free sale status of the applied product in country of origin. ➢ Copy of GMP certificate dated 05.11.2019 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea. (Original legalized in **Melen-Pro Oral Powder** dossier) ➢ Copy of letter of authorization (LOA) dated 10-11-2020 to M/s Ghazi Brothers Karachi from PLH for the applied product. (Original legalized in **Melen-Pro Oral Powder** dossier)

	Remarks of the Evaluator [X]	Firm has provided 24-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 2ml and 4ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • 06-month accelerated stability studies data of three batches at zone IV-A conditions.
	Decision: Deferred for following: • **Choice of only one pack size/ fill volume** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **06-month accelerated stability studies data of three batches at zone IV-A conditions.**	
119.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name and address of marketing authorization holder	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name of exporting country	Korea
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12863 Dated 03-05-2021
	Fee including differential fee	Rs: 50,000 Dated 03-05-2021
	Brand Name +Dosage Form + Strength	Melen-Pro Oral Powder
	Composition	Each gram contains: Melengestrol Acetate…0.22mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1000gm, 5000gm, 10000gm
	International availability	N/A
	Me-too status	**Could not be confirmed**

	Detail of certificates attached	➢ Originally legalized COPP No. M2015795 dated 08-12-2020 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea confirms free sale status of the applied product in country of origin. ➢ Original legalized GMP certificate dated 05.11.2019 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea. ➢ Original legalized letter of authorization (LOA) dated 10-11-2020 to M/s Ghazi Brothers Karachi from PLH for the applied product.
	Remarks of the Evaluator [X]	Firm has provided 24-month real time stability studies data of three batches at conditions **30ºC, 60% RH**. **Target species:** Heifer **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.
	Decision: Deferred for following: • **Choice of only one pack size/ fill volume** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.**	

SALATEEN WASEEM PHILIP
DEPUTY DIRECTOR PE&R

Item No 04: <u>New DML Veterinary</u>

120.	Central Licensing Board in its 295th meeting held on 11th January 2024 approved the grant of DML (afresh) No. 000449 (by way of formulation) for Veterinary drug products to M/s Hirra Pharmaceutical Laboratories (Private) Limited located at 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore, with following sections: - i. Oral Powder Section (General / antibiotics) – Veterinary ii. Oral Liquid Section (General / Antibiotics) – Veterinary	
	Oral Powder Section (General / antibiotics) – Veterinary	
	Name and address of manufacturer / Applicant	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra O.T 90% Powder

	Composition	Each kg contains: Oxytetracycline HCl ……. 900 gm
	Diary No. Date of R& I & fee	Dy. No 1280 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 88136131805 dated 19/01/2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	500 gm, 1 kg, 5 kg, 25kg.
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	HIRRA O.T. 90% POWDER. (Reg. # 44907)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with USP specifications.	
121.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra C.C.N 2000 Powder
	Composition	Each 1000 gm contains: Chlortetracycline HCl ……. 80 gm Neomycin Sulphate ……. 70 gm Colistin Sulphate ……... 4 gm
	Diary No. Date of R& I & fee	Dy. No 1278 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 65974266199 dated 19/01/2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	1 kg, 2.5 kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	N.C.C 154 Powder (Reg. # 48253)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
122.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra AF-2000 Powder
	Composition	Each 1000 gm contains: Amprolium HCl ……. 200 gm Furaltadone HCl …….200 gm Vitamin A ……... 4000,000 I.U Vitamin D …… 2000,000 I.U Vitamin K3 ……... 10 gm
	Diary No. Date of R& I & fee	Dy. No 1279 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 632168245 dated 19/01/2024
	Pharmacological Group	Sulpha drug

	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100gm, 250gm, 1kg & 2.5 kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Vety Ampro Plus Powder (Reg. # 46663)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
123.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Tylo Plus W.S Powder
	Composition	Each kg contains: Tylosin (as tartrate) ……..... 60 gm Furaltadon HCl ……... 150 gm Erythromycin Thiocyanate ……... 40 gm
	Diary No. Date of R& I & fee	Dy. No 1288 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip# 569832323936 dated 19/01/2024
	Pharmacological Group	Sulpha drug
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100gm, 250gm, 1kg & 2.5 kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Tefcon Powder by Amarant Pharma (Reg. # 43263)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
124.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra CTC Plus Powder
	Composition	Each kg contains: Choltetracycline HCl ……... 100 gm
	Diary No. Date of R& I & fee	Dy. No 1291 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 09646679 dated 19/01/2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100gm, 500gm & 1 kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	C-TETRA-45 POWDER by Epla Laboratories (Reg. # 6302)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with USP specifications	
125.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)**

		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
	Brand Name +Dosage Form + Strength	Hirra CTC Plus Powder
	Composition	Each kg contains: Trichlorphon 98% w/w
	Diary No. Date of R& I & fee	Dy. No 1293 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 36913761839 dated 19/01/2024
	Pharmacological Group	Skin antiseptic
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	500gm & 1 kg
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Seguvan Powder by Symans Pharmaceuticals (Pvt.) Ltd. (Reg. # 23442)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
126.	**Oral Liquid Section (General / Antibiotics) – Veterinary**	
	Name and address of manufacturer / Applicant	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra Darvisul Liquid
	Composition	Each 100ml contains: Sulphaquinoxaline ……. 2.56 gm Diaveridine ……. 0.64 gm
	Diary No. Date of R& I & fee	Dy. No 1282 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 9555259166 dated 19/01/2024
	Pharmacological Group	Sulfonamides
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100ml, 250ml, 500ml & 1 Liter.
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Darviexcel Oral Solution by Mediexcel Pharmaceuticals (Reg. # 31408)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
127.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Zan Suspension
	Composition	Each 100 ml contains: Levamisole HCl ……... 1.5% w/v Oxyclozanide ……... 3.0% w/v Cobalt Sulphate …… 382 mg
	Diary No. Date of R& I & fee	Dy. No 1284 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide

		Slip # 66681332 dated 19/01/2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100 ml, 250 ml, 450 ml & 1 liter
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Biozan Plus Suspension by Biorex Pharmaceuticals (Reg. # 31532)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
128.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449) 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra Fluke-Nil Drench
	Composition	Each 100 ml contains: Oxyclozanide ……... 3.4gm
	Diary No. Date of R& I & fee	Dy. No 1285 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 784388555 dated 19/01/2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100 ml, 250 ml,1 liter & 2 Liter
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Zanil Drench by ICI (Reg. # 2107)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
129.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449) 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Methassen
	Composition	Each 100 ml contains: Trimethoprim ……... 8 gm Sulphadiazine …… 40 gm
	Diary No. Date of R& I & fee	Dy. No 1287 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 8072691992 dated 19/01/2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	50 ml,250 ml & 1 Liter
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Trikail Suspension by Kalgon Argo Industries (Reg. # 10699)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	

130.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449) 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Abizole 2.5% Suspension
	Composition	Each ml contains: Albendazole …… 25 mg
	Diary No. Date of R& I & fee	Dy. No 1289 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 58073888909 dated 19/01/2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100 ml,250 ml, 500ml & 1 Liter
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Alben 2.5% w/v Suspension by Mehran International (Reg. # 19048)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
131.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449) 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Diluent
	Composition	Each ml contains: Monobasic Potassium Phosphate …… 0.37 mg Disodium Phosphate Dihydrate …… 0.72 mg Sodium Chloride …… 7.65 mg
	Diary No. Date of R& I & fee	Dy. No 1292 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Dy. No 2109562971 dated 19/01/2024
	Pharmacological Group	Diluent
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	50 ml & 200 ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Vaxi Drops by Grand Pharma (Reg. # 87070)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
132.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449) 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Enrogold CP 20% Liquid
	Composition	Each ml contains: Enrofloxacin …… 200 mg Colistin Sulphate …… 500 MIU
	Diary No. Date of R& I & fee	Dy. No 1294 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide

		Slip # 79936188 dated 19/01/2024
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	500 ml & 1000 ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Faxicol Oral Liquid by Farm Aid Group (Reg. # 88023)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
133.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449) 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Bvendaclose Suspension
	Composition	Each 100 ml contains: Albendazole …… 2.5 gm Closantel ……..…… 0.5 gm
	Diary No. Date of R& I & fee	Dy. No 1295 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 4724731384 dated 19/01/2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	60 ml, 120 ml, 500 ml & 1 liter
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Boxer 2.5% Suspension by Leads Pharma (Reg. # 28518)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
134.	**Name and address of manufacturer / Applicant**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited (DML # 000449) 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Livesole Suspension
	Composition	Each 100 ml contains: Levamisole HCl ……..……. 25mg
	Diary No. Date of R& I & fee	Dy. No 1296 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 73310089 dated 19/01/2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100 ml, 450 ml & 1 liter
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Levozid worm drench by PDH (Reg. # 28536)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	
135.	**Name and address of**	**M/s Hirra Pharmaceutical Laboratories (Private) Limited**

	manufacturer / Applicant	**(DML # 000449)** **1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.**
	Brand Name +Dosage Form + Strength	Hirra-Faxazol Oral Drench
	Composition	Each 100 ml contains: Oxfendazole ……..……. 2.265gm
	Diary No. Date of R& I & fee	Dy. No 1297 dated 22-01-2024 Rs. 30,000/- *(Form 5)* vide Slip # 970720052 dated 19/01/2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & demanded price	100 ml, 450 ml & 1 liter
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Ozox Suspension (Reg. # 28597)
	GMP status	New License
	Remarks of the Evaluator.	
	Decision: Registration Board approved the product with innovator's specifications	

EXPORT FACILITATION DESK

Item No. I: New Registration Cases

Case No.01: Registration of Drug (s) of M/s Trigon Pharmaceuticals (Pvt.) Ltd, 8-Km Thoker Raiwind Road, Lahore, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-5/92-Lic dated 10-08-2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 11-01-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
i.	Royal 150mg ER Tablet Each film coated ER tablet contains: Tapentadol HCl.....150mg	Purchase order from Togo	Dy. No. 1275(18.12.2023) Rs.75,000/- 11.11.2023)

Decision:

Registration Board deferred the case for confirmation of quantitative composition of API or its salt form from the firm.

Case No.02: Registration of Drug (s) of M/s Reign Pharmaceuticals PCSIR, KLC (Pvt.) Ltd, TBIC Building-1 PCSIR Laboratories complex, Shahrah-e-Dr, Salim-uz- Sidduqui, Off University Road, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-4/2010-Lic dated 30-06-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 11-11-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Empalin Tablet 25mg/5mg Each film coated tablet contains: Empagliflozin.....25mg Linagliptin.....5mg	Diampa LT tablet by M/s Getz	Dy. No. 1275(18.12.2023) Rs.30,000/- 31.10.2023)
2.	Empalin Tablet 10mg/5mg Each film coated tablet contains: Empagliflozin.....10mg Linagliptin.....5mg	Diampa LT tablet by M/s Getz	Dy. No. 1275(18.12.2023) Rs.30,000/- 31.10.2023)

Remarks:

The aforementioned brand names applied by the firm resemble with already registered brand names "Empalozin" of M/s Bio-Labs (Pvt.) Ltd. The firm has submitted that brand name is registered Trade Mark in Azerbaijan and requested to grant them the same name.

Decision:

Keeping in view, the Trade Mark registration of brand name in Country of Import, Registration Board approved above product exclusively for Export Purpose to Azerbaijan only. Registration Board further constituted following Committee to make a guidance document for grant of brand names:

1. **Director Drug Testing Laboratory, Peshawar.**
2. **Director Drug Testing Laboratory, Quetta.**
3. **Mr. Ghulam Mujtaba, Deputy Director, IPO, Islamabad.**
4. **Deputy Director RRR, DRAP Islamabad.**

Case No.03: Registration of Drug (s) of M/s Genome Pharmaceuticals (Pvt.) Ltd, 16/1, Phase-Iv, Industrial Estate, Hattar, Haripur, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 3-7/95-Lic dated 07-07-2021

GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 25-05-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Hco Tablet Each film coated tablet contains: Sodium Bicarbonate.....1000mg	Purchase order from Myanmar	Dy. No. 1462(18.12.2023) Rs.75,000/- (06.11.2023)

Decision:

Registration Board deliberated that the aforementioned formulation is neither available in Pakistan nor in RRAs, however, the said formulation does not require any special manufacturing conditions. Therefore, to increase the Export Revenue of the country, Registration Board approved the product exclusively for Export Purpose only.

Item No. II: Miscellaneous/ Deferred Cases

Case of 107-PRVC

Case No.01: Registration of Drug (s) of M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159, S.I.T.E. super Highway, Karachi,for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 182-1503/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided (Page-1491/C). Approval of relevant section verified from cGMP inspection report dated 18-03-2022 (Page 1492-1494/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 18-03-2022 (Page 1492-1494/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 1495-1504/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Nystat Oral Drops (100,000 IU/ml) Each ml contains: Nystatin USP.....100,000IU	Nilstat by M/s ICI	Dy. No. 1130/23 (22.09.2023) Rs.30,000/- (12.09.2023)

Decision of 107th PRVC:

"The Chairman Registration Board on recommendation of Committee considered the case and acceded to request of the firm for registration of above-mentioned products for Export Purpose Only subject to submission of more brand names for product at sr. no. 177."

The aforementioned brand name is registered in name of M/s Pliva Pakistan (Pvt.) Ltd. The firm has also submitted the copy of NOC from M/s Pliva Pakistan. But, M/s Pliva is not changing its brand name and submitted the following justification:

"M/s Pliva is the official manufacturer of Nystat Oral Drops for Royal Group for many exporting countries. Moreover, M/s Royal Group usually receives orders from exporting countries of a single product in large quantities, which is not possible to fulfill the demand of different countries by a single manufacturer that is why Royal Group splits the orders into multiple manufacturers for a single product country-wise. Nystat Drops is registered in our name but the product owner is Royal Group."

M/s Pliva Pakistan has requested to grant registration to M/s Swiss Pharma with brand name "Nystat Drops".

Decision:

Registration Board deferred the case for submission of following:

- **Application for change of brand name of Nystat Drops by M/s Pliva Pakistan**
  OR
- **More brand names by M/s Swiss Pharma Karachi which do not resemble with already registered products.**

Case of 104-PRVC

Case No.02: Registration of Drug (s) of M/s PharmEvo (Pvt.) Ltd, A-29, North western Industrial Zone Port Qasim, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 501-526& 711-758&937-1009& 1329-1348/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided (Page-507/C). Approval of relevant section verified from letter No. F 2-1-/98-Lic dated 21-02-2018 (Page 508-511/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 23-06-2022 (Page 512/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 513-527/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Linvesta 5mg Tablet Each film coated tablet contains: Linagliptin.....5mg	Lina 5mg tablet by M/s CCL	Dy. No. 778/23 (18.07.2023) Rs.30,000/- (21.06.2023)
2.	Linvesta-Emp 10+5mg Tablet Each film coated tablet contains: Empagliflozin.....10mg Linagliptin.....5mg	Linjar 5/10mg tablet by M/s CCL	Dy. No. 738/23 (18.07.2023) Rs.30,000/- (21.06.2023)
3.	Linvesta-Emp 25+5mg Tablet Each film coated tablet contains: Empagliflozin.....25mg	Linjar 25/5mg tablet by M/s CCL	Dy. No. 741/23 (18.07.2023)

	Linagliptin.....5mg		Rs.30,000/- (21.06.2023)

Decision of 104th PRVC:

"The Chairman Registration Board on recommendation of Committee considered the case and deferred request of the firm for products at Sr. No. 105-107 for more brand names due to resemblance of applied names."

UPDATED STATUS

The aforementioned brand names are already registered in name of M/s Wilshire Laboratories. However, the firm has submitted **Purchase Order (PO) from Guatemala** having above brand names and requested to grant them the same names.

Decision:

Registration Board deferred the case for submission of more brand names which do not resemble with already registered products.

Case of 108-PRVC

Case No.03: Registration of Drug (s) of M/s PharmEvo (Pvt.) Ltd, A-29, North western Industrial Zone Port Qasim, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 523-541& 644-662&678-688/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided (Page-530/C). Approval of relevant section verified from letter No. F 2-1-/98-Lic dated 21-02-2018 (Page 531/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 23-06-2022 (Page 533/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 535-542/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
2.	UFI 5mg Tablet Each film coated tablet contains: Solifenacin Succinate……5mg (corresponding to 3.8 mg solifenacin)	Solifen tablet by M/s Getz	Dy. No. 1241/23 (17.10.2023) Rs.30,000/- (10.10.2023)
3.	UFI 10mg Tablet Each film coated tablet contains: Solifenacin Succinate……10mg (corresponding to 7.5 mg solifenacin)	Solifen tablet by M/s Getz	Dy. No. 1240/23 (17.10.2023) Rs.30,000/- (10.10.2023)

Decision of 108th PRVC:

The Chairman Registration Board on recommendation of Committee considered the case and acceded to request of the firm for registration of products at sr. no. 56-57 for Export Purpose Only subject to submission of more brand names (which do not resemble with already registered drugs).

UPDATED STATUS

The aforementioned brand names are already registered in name of M/s Titlis Pharma. However, the firm has submitted **Purchase Order (PO) from Guatemala** having above brand names and requested to grant them the same names.

Decision: Registration Board deferred the case for submission of more brand names which do not resemble with already registered products.

Item No. III. Division of Biological Evaluation & Research

Sr. No.	Deputy Director	Designated No.	No. of Cases
1.	Mr. Muhammad Kashif	DD-I	21
2.	Ms. Haleema Shareef	DD-II	14
3.	Ms. Anam Saeed	DD-III	5
4.	Mr. Muhammad Kashif (Additional Agenda)	DD-I	04
Total			**44**

New/ Under Registration Cases:

Priority / Out of Queue consideration of Heparin & Enoxaparin Injections

I. DRAP Authority in its 144th meeting held on 26-08-2022 while considering the shortage of Heparin & Enoxaparin injections decided as follows:

"The Authority, as a one-time exercise, approved out of queue consideration of submitted registration applications of following drugs in order to ensure their smooth and continuous supply in the market:

Paracetamol (Tablets, lnfusion and Syrup / Suspension), Albumin bound Paclitaxel lnjection, Heparin and Enoxaprin lnjection. PE&R and BE&R Divisions are advised to process the cases of abovementioned drugs without waiting for formal approval of minutes."

II. DRAP Authority in its 165th meeting held on 20-07-2023 approved out of queue consideration of submitted registration applications of following drugs

Heparin, Anti-D, Streptokinase Injection

III. DRAP Authority in its 178th meeting held on 23-01-2024 approved out of queue consideration of submitted registration applications of following drugs

Heparin, Anti-D, Streptokinase Injection and Insulin

Imported Heparin Injection from non-Reference countries:
Molecule: Heparin Sodium
Evaluator: Mr. Muhammad Kashif

1.	**Name, address of Applicant / Importer**	M/s Himmel Pharmaceuticals (Pvt.) Ltd. Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore Address of go-down: N/A Validity: 06-02-2024 Status: License to sell drugs as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Duopharma (M) SDN. BHD. Lot 2599, Jalan Seruling 59 Kawasan 3, Taman Klang Jaya 41200 Klang, Selangor, Malaysia.
	Name, address of manufacturer(s)	M/s Duopharma (M) SDN. BHD. Lot 2599, Jalan Seruling 59 Kawasan 3, Taman Klang Jaya 41200 Klang, Selangor, Malaysia.

	Name of exporting country	Malaysia
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (1435/2022) issued by Pharmaceutical Services Division, Ministry of Health Malaysia Lot 36, Jalan Profesor Diraja Ungku Aziz, 46200 Petaling Jaya Selangor, Malaysia dated 1st August, 2020. The certificate confirm that the product is actually on the market in the exporting country and facilities and operations conform to GMP as recommended by WHO. The certificate is valid till 31-07-2025.
	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement from manufacturer abroad hereby authorizes M/s Himmel pharmaceuticals (Pvt) Ltd., Lahore as their exclusive agent to register and market our following product in the territory of Pakistan.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Diary No. 1468, Dated: 21-09-2023
	Details of fee submitted	Rs: 150,000/- Dated: 04-10-2023 Deposit Slip No. 7578078757
	The proposed proprietary name / brand name	UNIHEPA 5000 IU/ ML INJECTION (5ML VIAL)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Heparin Sodium……..25000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Finished product specifications	BP specifications
	Proposed Pack size	10’s × 5 ml vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store below 30°C
	Reference Regulatory Authorities	Heparin sodium 25000 IU / 5ml solution for Injection, USFDA Approved.

	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Adeste Indústria de Produtos Animais LTD Rua Paes Leme, 524, 6º andar Grupo 63 - CEP 054 24 904 Pinheiros – SãoPaulo – Brazil.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (Bovine Mucosa).
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches at long term conditions at 30℃ ± 2℃ / 75% RH ± 5% RH for 36 months. The accelerated stability data is conducted at 40°C±2℃ / 60%±5%RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method Validation / verification of the product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	Unihepa 5000IU/mL Injection (5mL vial) is packed in 6mL, 6R Type 1 Clear vial with grey rubber stopper with silver and 20mm flip off seal 'Blue'. Then 10 vials of Unihepa 5000 IU/mL Injection (5mL Vial) are packed into a clear PVC tray in one unit carton with a package insert Included.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Heparin Injection at accelerated and real time conditions. The real time stability data conducted at 30°C ± 2°C / 75% RH ± 5%RH for 36 months and accelerated stability data conducted at 40°C ± 2°C/75% RH ± 5%RH for 06 months for 3 batches 192802L (Upright) 192802L (Inverted) 200050L (Upright) 200050L (Inverted) 200660T (Upright) 200660T (Inverted)

	Remarks of Evaluator	• Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
2.	Name, address of Applicant / Importer	**M/s PAK CHINA INTERNATIONAL,** 498-C Feroz Shah Mehta Road, Karachi.
	Details of Drug Sale License of importer	License No: 0117 Address: 498-D Hume Road, Quaideen Colony, Near 3 Star Hall, Jamshed Road, Karachi Validity: 18-04-2023.
	Name and address of marketing authorization holder (abroad)	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech Industry Garden, Jining High and New Technology Industries Development Zone, Jining, Shandong Province, P.R. China.
	Name, address of manufacturer(s)	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech Industry Garden, Jining High and New Technology Industries Development Zone, Jining, Shandong Province, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	CoPP: The firm has submitted original, legalized CoPP (Shandong2036072) issued by Shandong Provincial Medical Products Administration. The certificate confirm that the product is actually on the market in the exporting country and facilities and operations conform to GMP as recommended by WHO. The certificate is valid till 03-12-2024.
	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement from manufacturer abroad hereby authorizes M/s Pak China International, Karachi to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only

	Dy. No. and date of submission	Diary No. 804, Dated: 06-10-2023
	Details of fee submitted	Rs: 150,000/- Dated: 04-10-2023 Deposit Slip No. 640275156
	The proposed proprietary name / brand name	HEPARIN INJECTION 5mL/25000IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL vial contains: Heparin Sodium……..25000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Finished product specifications	BP specifications
	Proposed Pack size	1 × 5 mL vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store below 30°C
	Reference Regulatory Authorities	Heparin sodium Injection, USFDA Approved.
	For generic drugs (me-too status)	PINE 5000 IU/5mL injection (Heparin sodium) by; HSC
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Dongying Tiandong Pharmaceutical Co Ltd. Address: No. 1236, Nan-er Road, Dongying City, Shandong, P.R. China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches at long term conditions at 25°C ± 2°C / 60% RH ± 5% RH for 18 months. The accelerated stability data is conducted at 40°C±2°C / 60%±5%RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications,

		reference standard or materials, container closure system and stability.
	Analytical method Validation / verification of the product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	5mL vial low borosilicate glass tubing
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Heparin Injection at accelerated and real time conditions. The real time stability data conducted at 30°C ± 2°C / 65% RH ± 5%RH for 36 months and accelerated stability data conducted at 40°C ± 2°C/75% RH ± 5%RH for 06 months for 3 batches. 170426 170427 170428
	Remarks of Evaluator	• Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin. • **The product was already registered with Pak china International (Reg # 013266) dated 5th July 1992 with same exporter as applied in the instant case i.e. Ningbo Nuobai Pharmaceutical Co.,Ltd, China**, However, the firm did not submit the renewal application after 2007. As per SRO when the renewal is submitted after the lapse of one year of due date of submission of renewal application, the product is automatically deregistered. Therefore, the firm has submitted new application.
Previous Decision: Deferred for the clarification regarding the availability in the country of origin (M-331).		
Previous Decision: Registration Board deferred the case for evidence of availability of product in the country of origin or in RRA or in three European countries from same manufacturer (M-332). **Evaluation by BE&R:** The firm has submitted reply from manufacturer abroad stating that: *"We have applied for registration of Heparin Injection 5ML/25000 IU through sole agents in Pakistan M/s Pak China International, Karachi. In P.R. China, Heparin injection is registered in 5000 IU/1ML. The strength is same. As per requirement of various countries including Pakistan, we have also been manufacturing Heparin Injection 5ML/25000 IU and exporting to various countries 01) PERU, 02) UZBEKISTAN, 03) KYOGYZSTAN, 04) ETHOPIA, 05) MAURITANIA, 06) BOLIVIA, 07) PHILLIPINES and 08) NICARAGUA.*		
Decision: The Registration Board, after detailed deliberation and keeping in view valid legalized CoPP indicating product availability in country of origin;, approved the product subject to current Import Policy for finished drugs.		

Molecule: Enoxaparin Sodium
Evaluator: Mr. Muhammad Kashif

3.	**Name, address of Applicant / Importer**	M/s Himmel Pharmaceuticals (Pvt.) Ltd. Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore

		Address of go-down: N/A Validity: 06-02-2024 Status: License to sell drugs as a Distributor
	Name and address of marketing authorization holder/ Product License Holder (abroad)	M/s ATABAY KIMYA SAN. ve TIC. A.S. cibadem Koftuncu sok. No :1 34718 Kadikoy / ISTANBUL – TURKEY.
	Name, address of manufacturer(s)	M/s ATABAY ILAC FABRIKASI. A.S Acibadem Koftuncu sok. No : 1 34718 Kadikoy / ISTANBUL - TURKEY.
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (No.2023/3160) dated 25-07-2023 valid upto 24-07-2025 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey. The CoPP specifies free sale status of the product in country of export along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: 3 years) **GMP:** The firm has also submitted Original legalized GMP No. TR/GMP/2022/27 inspection of this manufacturer was conducted on 10.12.2021 and 13-16.12.2021 and concluded that it is considered that it complies with the requirements of cGMP.
	Details of letter of authorization / sole agency agreement	rm has submitted letter of product specific authorization from Member of Board of M/s ATABAY KIMYA SAN. ve TIC. A.S. According to the letter, the firm ATABAY KIMYA SAN. ve TIC. A.S. certify that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address "Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market 'Enox 8000 Anti-XA IU/0.8 ml Pre-Filled Syringes (Enoxaparin Sodium 60mg)' in the territory of Pakistan. The letter was issued on 11-11-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	y. No.358: Dated 07-09-2023
	Details of fee submitted	Rs. 150,000/-; (Deposit slip # 3329833535)
	The proposed proprietary name / brand name	Enox 8000 Anti-XA IU/0.8 mL Pre-Filled Syringe

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Pre-Filled Syringe (0.8mL) contains: Enoxaparin Sodium ……80mg
	Dosage form of applied drug	Pre-Filled Syringe
	Pharmacotherapeutic Group of (API)	Anti-Thrombotic (Low molecular weight heparin)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Pack Size: 2's PFS
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	30°C ± 2°C
	The status in reference regulatory authorities	ovenox injection of Sanofi Aventis (USA.)
	For generic drugs (me-too status)	exane Injection of Sanofi Aventis
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Hebei Changshan Biochemical Pharmaceutical Co., Ltd., Address: No.71, Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Enoxaparin Sodium at accelerated (40°C ± 2°C, 75% ± 5% RH) for 06 months and real time conditions (25°C± 2°C, 60% ± 5% RH) for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the tests for specifications meet the requirements of USP Monograph, and therefore validation reports are presented.

	Container closure system of the drug product	Primary Packaging: Syringes (Type I glass), Hypodermic needle (Passivated stainless-steel needle) with a Plunger stopper (Chlorobutyl elastomeric stopper) and Plunger rod (Polypropylene, polystyrene or polyethylene). Secondary package: PVC/Pet/Easy peel Blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40ºC ± 2 ºC, 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ± 2ºC, 65% ± 5 %RH for 36 months. Batch no. 181086 Batch no. 173027 Batch no. 162460
	Module-IV	*The nonclinical overview aims to describe the pharmacological, pharmacokinetic and toxicological features of the product by compiling research performed on preclinical experimental animals and other live materials in vivo and in vitro with enoxaparin that is the active agent of* Enox 8000 anti-Xa IU/0.8 ml Pre-filled Syringes, which is used in venous thromboembolism prophylaxis (prevention of clotting in veins), especially in certain procedures, in venous thromboembolism prophylaxis of bedridden patients, in prevention of thrombosis in extracorporeal circulation during hemodialysis, in treatment of deep vein thrombosis, which is accompanied or not accompanied by a pulmonary embolism, in treatment of unstable angina and non-Q myocardial infarct.
	Module-V	• An open-label, randomized, single-dose, two-way, crossover pivotal bioequivalence study comparing Enox 10000 anti-Xa IU/ 1,0 ml solution for injection in pre-filled syringes, Atabay Kimya San. ve Tic. A.Ş., Turkey, containing enoxaparin sodium vs. CLEXANE 10.000 I.E. (100 mg)/1ml Injektionslösung in einer Fertigspritze, Sanofi Aventis Deutschland GmbH, Germany in healthy adult volunteers under fasting conditions.
4.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd.** Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore Address of go-down: N/A Validity: 06-02-2024 Status: License to sell drugs as a Distributor
	Name and address of marketing authorization holder/ Product License Holder (abroad)	ATABAY KIMYA SAN. Ve TIC. A.S. cibadem Koftuncu sok. No :1 34718 Kadikoy / ISTANBUL / TURKEY
	Name, address of manufacturer(s)	M/s ATABAY ILAC FABRIKASI. A.S Acibadem Koftuncu sok. No :1 34718 Kadikoy / ISTANBUL / TURKEY.
	Name of exporting country	Turkey

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: The firm has submitted original, legalized CoPP (No.2022/1503) dated 27-05-2022 valid upto 27-05-2024 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey. The CoPP specifies free sale status of the product in country of export along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:3years) GMP: • The firm has also submitted Original legalized GMP No. TR/GMP/2022/27 inspection of this manufacturer was conducted on 10.12.2021 and 13-16.12.2021 and it is considered that it complies with the requirements of cGMP.
	Details of letter of authorization / sole agency agreement	rm has submitted letter of product specific authorization from Member of Board of M/s ATABAY KIMYA SAN. Ve TIC. A.S. According to the letter, the firm ATABAY KIMYA SAN. Ve TIC. A.S. certify that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address "Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market 'Enox 6000 Anti-XA IU/0.6 ml Pre-Filled Syringes (Enoxaparin Sodium 60mg)' in the territory of Pakistan. The letter was issued on 11-11-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	y. No.7184: Dated 13-03-2023
	Details of fee submitted	Rs. 150,000/- ; Dated 14-02-2023
	The proposed proprietary name / brand name	Enox 6000 Anti-XA IU/0.6 mL Pre-Filled Syringes
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Pre-Filled Syringe contains: Enoxaparin Sodium ……60mg
	Dosage form of applied drug	Pre-Filled Syringe
	Pharmacotherapeutic Group of (API)	Anti-Thrombotic (Low molecular weight heparin)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Pack Size: 2 PFS
	Proposed unit price	As per SRO

	Shelf Life	36 months
	Storage Conditions	30°C ± 2ºC
	The status in reference regulatory authorities	ɔvenox (USA.)
	For generic drugs (me-too status)	exane 60mg (Germany)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Hebei Changshan Biochemical Pharmaceutical Co., Ltd. Address: No.71, Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Enoxaparin Sodium at accelerated (40ºC ± 2 ºC, 75% ± 5% RH) and real time conditions (25°C± 2°C, 60% ± 5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the tests for specifications meet the requirements of USP Monograph, and therefore validation reports are presented.
	Container closure system of the drug product	Primary Packaging: Syringes (Type I glass), Hypodermic needle (Passivated stainless-steel needle) with a Plunger stopper (Chlorobutyl elastomeric stopper) and Plunger rod (Polypropylene, polystyrene or polyethylene). Secondary package: PVC/Pet/Easy peel Blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40ºC ± 2 ºC, 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ± 2, 65% ± 5 %RH for 36 months. Batch no. 211734 Batch no. 211741 Batch no. 211743

	Module-IV	*The nonclinical overview aims to describe the pharmacological, pharmacokinetic and toxicological features of the product by compiling research performed on preclinical experimental animals and other live materials in vivo and in vitro with enoxaparin that is the active agent of* Enox 8000 anti-Xa IU/0.8 ml Pre-filled Syringes, which is used in venous thromboembolism prophylaxis (prevention of clotting in veins), especially in certain procedures, in venous thromboembolism prophylaxis of bedridden patients, in prevention of thrombosis in extracorporeal circulation during hemodialysis, in treatment of deep vein thrombosis, which is accompanied or not accompanied by a pulmonary embolism, in treatment of unstable angina and non-Q myocardial infarct.
	Module-V	• An open-label, randomized, single-dose, two-way, crossover pivotal bioequivalence study comparing Enox 10000 anti-Xa IU/ 1,0 ml solution for injection in pre-filled syringes, Atabay Kimya San. ve Tic. A.Ş., Turkey, containing enoxaparin sodium vs. CLEXANE 10.000 I.E. (100 mg)/1ml Injektionslösung in einer Fertigspritze, Sanofi Aventis Deutschland GmbH, Germany in healthy adult volunteers under fasting conditions.
5.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd.** Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore Address of go-down: N/A Validity: 06-02-2024 Status: License to sell drugs as a Distributor
	Name and address of marketing authorization holder/ Product License Holder (abroad)	ATABAY KIMYA SAN. Ve TIC. A.S. Acibadem Koftuncu sok. No :1 34718 Kadikoy / ISTANBUL / TURKIYE.
	Name, address of manufacturer(s)	ATABAY ILAC FABRIKASI. A.S Acibadem Koftuncu sok. No :1 34718 Kadikoy / ISTANBUL / TURKIYE.
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No.2022/1504) dated 27-05-2022 valid up to 27-05-2024 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey. The CoPP specifies free sale status of the product in country of export along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:3years) **GMP:** The firm has also submitted Original legalized GMP No. TR/GMP/2022/27 inspection of this manufacturer was conducted on 10.12.2021 and 13-16.12.2021 and it is considered that it complies with the requirements of cGMP.

	Details of letter of authorization / sole agency agreement	rm has submitted letter of product specific authorization from Member of Board of M/s ATABAY KIMYA SAN. Ve TIC. A.S. According to the letter, the firm ATABAY KIMYA SAN. Ve TIC. A.S. certify that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address "Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market 'Enox 4000 Anti-XA IU/0.4 ml Pre-Filled Syringes (Enoxaparin Sodium 40mg)' in the territory of Pakistan. The letter was issued on 11-11-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 7185; Dated 13-03-2023
	Details of fee submitted	Rs. 150,000/- ; (Slip # 25133234658)
	The proposed proprietary name / brand name	Enox 4000 Anti-XA IU/0.4 mL Pre-Filled Syringes
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Pre-Filled Syringe contains: Enoxaparin Sodium ……40mg
	Dosage form of applied drug	Pre-Filled Syringe
	Pharmacotherapeutic Group of (API)	Anti-Thrombotic (Low molecular weight heparin)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Pack Size: 2 PFS
	Proposed unit price	Retail price As per SRO
	Shelf Life	36 months
	Storage Conditions	30ºC ± 2ºC, 65% ± 5% RH
	The status in reference regulatory authorities	Lovenox (USA.)
	For generic drugs (me-too status)	Clexane 40mg (Germany)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical

		procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Hebei Changshan Biochemical Pharmaceutical Co., Ltd. Address: No.71, Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Enoxaparin Sodium at accelerated (40°C ± 2°C, 75% ± 5% RH) and real time conditions (25°C± 2°C, 60% ± 5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the tests for specifications meet the requirements of USP Monograph, and therefore validation reports are presented.
	Container closure system of the drug product	Primary Packaging: Syringes (Type I glass), Hypodermic needle (Passivated stainless-steel needle) with a Plunger stopper (Chlorobutyl elastomeric stopper) and Plunger rod (Polypropylene, polystyrene or polyethylene). Secondary package: PVC/Pet/Easy peel Blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40°C ± 2°C, 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30 ºC ± 2 ºC, 65% ± 5 %RH for 36 months. Batch no: 200112 Batch no: 170021, Batch no: 200112,
	Module-IV	*The nonclinical overview aims to describe the pharmacological, pharmacokinetic and toxicological features of the product by compiling research performed on preclinical experimental animals and other live materials in vivo and in vitro with enoxaparin that is the active agent of* Enox 8000 anti-Xa IU/0.8 ml Pre-filled Syringes, which is used in venous thromboembolism prophylaxis (prevention of clotting in veins), especially in certain procedures, in venous thromboembolism prophylaxis of bedridden patients, in prevention of thrombosis in extracorporeal circulation during hemodialysis, in treatment of deep vein thrombosis, which is accompanied or not accompanied by a pulmonary embolism, in treatment of unstable angina and

		non-Q myocardial infarct.
	Module-V	• An open-label, randomized, single-dose, two-way, crossover pivotal bioequivalence study comparing Enox 10000 anti-Xa IU/ 1,0 ml solution for injection in pre-filled syringes, Atabay Kimya San. ve Tic. A.Ş., Turkey, containing enoxaparin sodium vs. CLEXANE 10.000 I.E. (100 mg)/1ml Injektionslösung in einer Fertigspritze, Sanofi Aventis Deutschland GmbH, Germany in healthy adult volunteers under fasting conditions.
6.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd.** Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore Address of go-down: N/A Validity: 06-02-2024 Status: License to sell drugs as a Distributor
	Name and address of marketing authorization holder/ Product License Holder (abroad)	ATABAY KIMYA SAN. Ve TIC. A.S. Acibadem Koftuncu sok. No :1 34718 Kadikoy / ISTANBUL / TURKIYE.
	Name, address of manufacturer(s)	ATABAY ILAC FABRIKASI. A.S Acibadem Koftuncu sok. No :1 34718 Kadikoy / ISTANBUL / TURKIYE.
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No.2023/3159) dated 25-07-2023 valid up to 24-07-2025 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey. The CoPP specifies free sale status of the product in country of export along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:3years) **GMP:** The firm has also submitted Original legalized GMP No. TR/GMP/2022/27 inspection of this manufacturer was conducted on 10.12.2021 and 13-16.12.2021 and it is considered that it complies with the requirements of cGMP.
	Details of letter of authorization / sole agency agreement	rm has submitted letter of product specific authorization from Member of Board of M/s ATABAY KIMYA SAN. Ve TIC. A.S. According to the letter, the firm ATABAY KIMYA SAN. Ve TIC. A.S. certify that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address "Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market 'Enox 4000 Anti-XA IU/0.4 ml Pre-Filled Syringes (Enoxaparin Sodium 40mg)' in the territory of Pakistan. The letter was issued on 11-11-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 359; Dated 07-09-2023
	Details of fee submitted	Rs. 150,000/- ; (Slip # 47504494628)
	The proposed proprietary name / brand name	Enox 2000 Anti-XA IU/0.2 mL Pre-Filled Syringes
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Pre-Filled Syringe contains: Enoxaparin Sodium ……20mg
	Dosage form of applied drug	Pre-Filled Syringe
	Pharmacotherapeutic Group of (API)	Anti-Thrombotic (Low molecular weight heparin)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Pack Size: 2 PFS
	Proposed unit price	Retail price As per SRO
	Shelf Life	36 months
	Storage Conditions	30ºC ± 2ºC, 65% ± 5% RH
	The status in reference regulatory authorities	Lovenox (USA.)
	For generic drugs (me-too status)	Clexane 20mg (Germany)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Hebei Changshan Biochemical Pharmaceutical Co., Ltd. Address: No.71, Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Enoxaparin Sodium at accelerated (40°C ± 2°C, 75% ± 5% RH) and real time conditions (25℃± 2℃, 60% ± 5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the tests for specifications meet the requirements of USP Monograph, and therefore validation reports are presented.
	Container closure system of the drug product	Primary Packaging: Syringes (Type I glass), Hypodermic needle (Passivated stainless-steel needle) with a Plunger stopper (Chlorobutyl elastomeric stopper) and Plunger rod (Polypropylene, polystyrene or polyethylene). Secondary package: PVC/Pet/Easy peel Blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40°C ± 2°C, 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30 ºC ± 2 ºC, 65% ± 5 %RH for 36 months. Batch no: 200138 Batch no: 190230, Batch no: 183108,
	Module-IV	*The nonclinical overview aims to describe the pharmacological, pharmacokinetic and toxicological features of the product by compiling research performed on preclinical experimental animals and other live materials in vivo and in vitro with enoxaparin that is the active agent of* Enox 8000 anti-Xa IU/0.8 ml Pre-filled Syringes, which is used in venous thromboembolism prophylaxis (prevention of clotting in veins), especially in certain procedures, in venous thromboembolism prophylaxis of bedridden patients, in prevention of thrombosis in extracorporeal circulation during hemodialysis, in treatment of deep vein thrombosis, which is accompanied or not accompanied by a pulmonary embolism, in treatment of unstable angina and non-Q myocardial infarct.
	Module-V	An open-label, randomized, single-dose, two-way, crossover pivotal bioequivalence study comparing Enox 10000 anti-Xa IU/ 1,0 ml Solution for injection in pre-filled syringes, Atabay Kimya San. Ve Tic.A.Ş., Turkey, containing enoxaparin sodium vs. CLEXANE 10.000 I.E. (100 mg)/1ml Injektionslösung in einer Fertigspritze, Sanofi Aventis Deutschland GmbH, Germany in healthy adult volunteers under fasting conditions
Data as per guidelines of 289th meeting of Registration Board; **For Finished Import:**		

Sr. No.	Required Documents	Documents Provided by the Firm
1.	Equivalence of physicochemical properties, such as: a. Molecular weight distribution using size exclusion chromatography	**a. Molecular weight and Molecular weight distribution** **Batch No.:** Brand product：6L186A Sample：L-RE181102-4-a'，L-RE181102-5-a'，L-RE181104-2-a' Mw <2000 2000-8000 >8000 6L186A 4191 18.21 72.55 9.24 L-RE181102-4-a' 4095 18.43 73.08 8.50 L-RE181102-5-a' 4117 18.14 73.22 8.63 L-RE181104-2-a' 4079 19.14 72.42 8.44 **Note:** The above enoxaparin sodium batches are from lab batches, Mw refers to weight-average molecular weight of enoxaparin sodium, <2000 refers to the percentage of enoxaparin having a molecular weight of less than 2000Da; 2000-8000 refers to the percentage of enoxaparin having a molecular weight ranging between 2000 and 8000 Da, >8000 refers to the percentage of enoxaparin having a molecular weight of higher than 8000Da. **Conclusion:** From the above data, we can conclude that the molecular weight and molecular weight distribution of enoxaparin made by CSBIO is similar with those of brand product. **1 Reference:** USP monograph-Enoxaparin sodium **2 Acceptance criteria:** Determine with Size exclusion chromatography, the weight-average molecular weight of Enoxaparin sodium is 3800~5000, in which,12.0%~20.0% have a molecular weight of less than 2000Da, 68.0%~82.0% have a molecular weight between 2000 Da and 8000 Da, NMT 18.0% have a molecular weight higher than 8000 Da. **3 Solution preparation** 3.1 Mobile phase (0.5M lithium nitrate solution): place 34.475 g of lithium nitrate into a 1L-beaker, add 1L of purified water, dissolve it completely, pass through a membrane filter of 0.22um before use. **3.2** Molecular weight calibrant A solution: take 1 vial of USP molecular weight calibrant A, dissolve in 1mL of mobile phase. **3.3** Molecular weight calibrant B solution: take 1 vial of USP molecular weight calibrant B, dissolve in 1mL of mobile phase. **3.4** Standard solution: take 10mg of USP enoxaparin sodium RS, dissolve in 1ml of mobile phase, the standard solution with concentration of 10mg/mL is obtained. **3.5** Test solution: take 10mg of sample, dissolve in 1mL of mobile phase, the test solution with concentration of 10mg/mL is obtained. **4** Chromatographic system **4.1** Instrument: Shimadzu LC-20AT HPLC, RI detector, column temperature: 30℃, flow rate: 0.6mnl/min **4.2** Column: TSK G3000SWX(300mm×7.8mm) in series

<table>
<tr>
<td></td>
<td></td>
<td>with TSK G3000SWXL(300mm×7.8mm).
4.3 Injection: respectively inject 20μL of Molecular weight calibrant A solution (single sample and single injection), Molecular weight calibrant B solution(single sample and single injection), standard solution (single sample and double injection) and test solution (single sample and single injection), record the chromatograms.
5 Data processing:
5.1 In the chromatograms for molecular weight calibrant A solution and molecular weight calibrant B solution, there are 4 peak times in A chromatogram, and 3 peak times for B chromatogram, according to the molecular weight specified in the standard leaflet, plot the retention time on the x-axis against the peak molecular weight on the y-axis, fit the data to a third-order polynomial curves, using suitable GPC software.
5.2 Using the same GPC software, determine the percentage of molecular weight for each test solution with same concentration, including the percentage of enoxaparin sodium chains with molecular weight lower than 2000 Da-*M2000*, the percentage of enoxaparin sodium chains with molecular weight in the range 2000~8000Da-*M2000~8000*, the percentage of Enoxaparin
sodium chains with molecular weights greater than 8000 Da- *M8000*.
5.3 System suitability requirement: the difference between the calculated Mw and labeled Mw of Enoxaparin sodium RS should be within 150Da.
6 Oligosaccharide chain length equivalence GPC: according to the following range, primarily study the percentage of different molecular weight range.
<table>
<tr><td>Degree of polymerization (dp)</td><td>Molecular weight range</td></tr>
<tr><td>dp2~dp6</td><td>min</td></tr>
<tr><td>dp8</td><td>1540-2030</td></tr>
<tr><td>dp10</td><td>2030-2555</td></tr>
<tr><td>dp12</td><td>2555-3140</td></tr>
<tr><td>dp14</td><td>3140-3780</td></tr>
<tr><td>dp16</td><td>3780-4460</td></tr>
<tr><td>dp18</td><td>4460-5190</td></tr>
<tr><td>dp20</td><td>5190-5875</td></tr>
<tr><td>dp22</td><td>5875-6645</td></tr>
<tr><td>dp22 end~8000</td><td>6645-8000</td></tr>
<tr><td>8000~10000</td><td>8000-10000</td></tr>
<tr><td>10000~12000</td><td>10000-12000</td></tr>
<tr><td>12000~14000</td><td>12000-14000</td></tr>
<tr><td>14000~16000</td><td>14000-16000</td></tr>
<tr><td>16000~18000</td><td>16000-18000</td></tr>
<tr><td>18000~</td><td>18000-max</td></tr>
</table>
</td>
</tr>
<tr>
<td></td>
<td>b. Chain mapping by cetyltrimethylammonium-coated</td>
<td>Spectral analyses have been utilized:</td>
</tr>
</table>

	strong anion exchange chromatography matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	**1H-NMR spectrum** **Nuclear Magnetic Resonance Spectrometry (1H-NMR, 13C-NMR)** Instrument: BRUKER AVANCE II 500 NMR spectrometer 1H resonance frequency: 500.13 MHz 13C resonance frequency: 125.76 MHz Solvent: Deuterium water (D2O) Internal standard: TSP **1H NMR** Taking the sample (batch No. NES141002) as example, the 1H NMR spectrum shows multiple peaks. Due to the high molecular weight of enoxaparin sodium, transverse relaxation time of the protons of various groups in the structure is very short, every multiple peak shows wide peak, it is difficult to make a clear attribution for most hydrogen signals. Therefore, only main groups are attributed and analyzed. The test results are given in table 1. **Table 1 ; 1H NMR results of the sample (batch No. NES141002)**

No.	δH(ppm)		Attribute
	Sample	USP standard	
1	2.047	2.046	-COCH3
2	3.287	3.285	GlcNS6S H2
3	3.789	3.789	GlcNS6S H4
4	4.108	4.105	IdoA2S H4
5	4.218	4.215	IdoA2S H3
6	4.346	4.345	IdoA2S H2
7	4.628	4.629	GlcA H1
8	4.823	4.821	IdoA2S H5
9	5.222	5.219	IdoA2S H1
10	5.411	5.415	GlcNS6S H1
11	5.507	5.507	ΔUA2S H1
12	5.987	5.986	ΔUA2S H4

13C-NMR Spectrum

Taking the sample (batch No. NES141002) as example. Enoxaparin sodium is polysaccharide that consists of disaccharide units, and these signals on 13C NMR can basically reflect the characteristics of the polysaccharide structure. Only main groups are attributed and analyzed. The test results are given in table 2.

Table 2 ; 13C NMR results of the sample (batch No. NES141002)

No.	δC(ppm)		Attribute
	Sample	USP standard	
1	23.79	23.80	GlcNAc-CH3
2	50.00	50.00	GlcNAc/ GlcNS C2
3	98.92	98.92	GlcNS6S C1
4	100.93	100.92	IdoA2S C1
5	107.80	107.81	ΔUA C4
6	146.59	146.59	ΔUA C5
7	170.88	170.88	ΔUA-COOH
8	176.38	176.39	UA-COOH

Analysis and Conclusion

The 1H NMR and 13C NMR spectra show that the structures of methyl group, carboxylate group, methine group and methylene group, etc. exist in the molecular structure, which conforms to the characteristics of enoxaparin sodium. Comparing the 1H-NMR spectrum and the 13C-NMR spectrum of the sample with those of the RS, a conclusion can be reached that both 1H-NMR spectrum and 13C-NMR spectrum of the sample are consistent with those of enoxaparin sodium RS

IR Spectrum

Instrument: BRUKER ALPHA FT-IR Spectrometer

KBr method

Taking the sample (batch No. NES141002) as example, the rest results are given in table 3.

Table 3 IR results of the sample (batch No. NES141002)

Brand (cm-1)		Type of vibration	Functional group
Sample	Standard		
3490.81	3490.00	ν_{O-H}	-OH
2945.97	2946.17	ν_{C-H}	-CH2-
1627.21	1627.37	$\nu_{C=O}$, asymmetrical	-C=O
1426.14	1426.04	$\nu_{C=O}$, symmetrical	C=O
1235.27	1234.98	$\nu_{S=O}$	-OSO3-
1038.08	1038.46	δ_{O-H}	O-H
889.83	889.82	ν_{C-O-S}	C2-OSO3-

Analysis and Conclusion

The infrared spectra show that structures of hydroxyl group, amide group, carboxylate group methine group and methylene group, etc. exist in the molecular structure, which conforms to the characteristics of enoxaparin sodium. The infrared spectrum of the sample is consistent with that of enoxaparin sodium RS.

UV Spectrum

UV Absorption spectrophotometry

Instrument: UV-2550 Ultraviolet-visible Spectrophotometer

Procedure

Prepare a solution of 0.5 mg/mL enoxaparin sodium in 0.01 mol/L hydrochloric acid, scan at the wavelength range of 190~600 nm by UV-VIS spectrophotometry. Take 0.01 mol/L hydrochloric acid as blank. The maximum absorption of sample solution is at 232.5nm, while that of reference solution is at 232.0nm.

Conclusion

The results show that the UV spectra of three batches of sample are consistent with that of enoxaparin sodium RS, the maximum absorption is at 231 nm, which comply with the characteristic absorption of enoxaparin sodium.

2.	Equivalence of heparin source material (i.e. heparin that is derived from porcine intestinal mucosa and that meets USP	Heparin source material is porcine intestinal mucosa. PCR of each batch of Heparin is carried out to prove that there is only porcine material.

	monograph standards for heparin sodium USP) and mode of depolymerization (i.e. cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	Conversion of Heparin Sodium to Enoxaparin Sodium is divided in four major steps comprising formation of **Heparin benzethonium salt, formation of Heparin benzyl ester, depolymerization and purification and lyophilization** of the product to give Enoxaparin Sodium. This method of production is the same for Lovenox / Clexane and Atabay Enox.
3.	Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by following: a. Capillary Electrophoresis (CE) b. Reverse phase high-performance liquid chromatography (RP-HPLC) c. Strong anion exchange HPLC (SAX-HPLC) d. Mass spectroscopy e. Nuclear magnetic resonance (NMR) spectroscopy. f. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.	• Disaccharide building block by Waters Spherisorb SAX-HPLC • Disaccharide analysis by Reversed phase ion pairing (RPIP)– • Disaccharide analysis by ultra-performance liquid chromatography (UPLC) • Disaccharide analysis by mass spectrometry (MS) • Oligosaccharide mapping by Hydrophilic interaction chromatography (HILIC) • Oligosaccharide mapping by Fourier transform (FT) MS • Oligosaccharide distribution by LC/MS method • The intact chains (mix of oligosaccharide and polysaccharide) analysis performed using LC-MS **Disaccharide Analysis** Introduction: LMWH is composed of repeating disaccharide units of variable structure. Exhaustive treatment of a LMWH with a mixture of three heparin lyases breaks it down to its disaccharide components. Comparison of the disaccharide composition of LMWH samples can be used to assess their structural similarity. **Enzymatic digestion:** From each stock solution a stock solution 5 □g of analyte could be taken. Heparin lyases I, II, and III (10 mU each, assayed prior to use) in 5 □l of 25 mM Tris, 500 mM NaCl, and 300 mM imidazole buffer (pH 7.4) were added to 5 □g of GAG sample in 25 □l of distilled water and incubated at 37 °C for 10 h to completely degrade the GAG sample. The products were recovered by centrifugal filtration using a YM-10 microconcentrator, and the heparin/HS disaccharides were recovered in the flowthrough and freeze-dried. The digested GAG disaccharides were re-dissolved in water to a concentration of 50 to 100 ng/2 □l for LC–MS analysis. **Reversed phase ion pairing (RPIP)–ultraperformance liquid chromatography (UPLC)– mass spectrometry (MS) analysis:** LC–MS analyses were performed on an Agilent 1200 2 LC/MSD instrument (Agilent Technologies,

		Wilmington, DE, USA) equipped with a 6300 ion trap and a binary pump followed by a ultraviolet (UV) detector equipped with a high pressure cell. The column used was an Acquity UPLC BEH C18 column (2.1 □□150 mm, 1.7 □m, Waters, Milford, MA, USA). Eluent A was water/acetonitrile (85:15, v/v), and eluent B was water/acetonitrile (35:65, v/v). Both eluents con- tained 12 mM TrBA and 38 mM NH4OAc with pH adjusted to 6.5 with HOAc. A gradient of solution A for 10 min followed by a linear gradient from 10 to 40 min (0–50% solution B) was used at a flow rate of 100 □l/min for disaccharide analysis. The column effluent entered the source of the ESI–MS for continuous detection by MS. The electrospray interface was set in negative ionization mode with a skimmer potential of-40.0 V, a capillary exit of -40.0 V, and a source temperature of 350 °C to obtain the maximum abundance of the ions in a full-scan spectrum (200–1500 Da). Nitrogen (8 L/min, 40 psi) was used as a drying and nebulizing gas. **Calibration:** Quantification analysis of heparin/HS disaccharides was performed using calibration curves constructed by separation of increasing amounts of unsaturated heparin/HS disaccharide standards (2, 5, 10, 15, 20, 30, 50, and 100 ng per disaccharide). Linearity was assessed based on the amount of disaccharide and peak intensity in MS. All analyses were performed in triplicate. **Conclusions:** All three products, Atabay enoxaparin, Lovenox, and Clexane had similar disaccharide compositions **<u>Bottom-up analysis (oligosaccharide mapping)</u>** Introduction: LMWH is a polydisperse mixture of oligosaccharide and polysaccharide chains of variable structure. Treatment of a LMWH with a single heparin lyase (heparin lyase II), which selectively cuts LMWH into small oligosaccharide fragments comprising an oligosaccharide map. Comparison of the oligosaccharide maps of LMWH samples can be used to assess their structural similarity. **Reagents:** Heparin lyase II was prepared by *E. coli* expression and purification of the recombinant *F. heparinum* heparin lyase II (EC# 4.2.2.X) was performed in our laboratory. **<u>Enzymatic digestion of LMWHs:</u>** Three lots of desalted LMWH samples (100 □g) from each manufacturer were dissolved in 100 □L of distilled water and completely digested by heparin lyase II (20 mU) at 35 °C for 2 h (longer digestion times of up to 12 h gave 3 similar results). Aliquots were immediately heated in a 100 °C water bath to stop the reaction and were then spun down at 12000 rpm for 5 min; supernatants were used directly for LC-MS analysis.

		Hydrophilic interaction chromatography (HILIC) LC electrospray ionization (ESI)-LTQOrbitrap-Fourier transform (FT) MS Analysis of Digested LMWHs: A Luna HILIC column (2.0 × 50 mm, 200 Å, Phenomenex, Torrance, CA) was used to separate the LMWHs. Mobile phase A was 5 mM ammonium acetate prepared with HPLC grade water. Mobile B was 5 mM ammonium acetate prepared in 98% HPLC grade acetonitrile with 2% of HPLC grade water. The gradient was used from 5% A to 70% A in 7 min then reset to 5% A at a flow rate of 250 L/min. The LC column was directly connected online to the standard ESI source of LTQ-Orbitrap XL FT MS (Thermo Fisher Scientific, San-Jose, CA). The source parameters for FTMS detection were optimized using Arixtra (a synthetic ultra LMWH from Sanofi-Aventis, Paris, France) to minimize the insource fragmentation and sulfate loss and maximize the signal/noise in the negative-ion mode. The optimized parameters, used to prevent in-source fragmentation, included a spray voltage of 4.2 kV, a capillary voltage of -40 V, a tube lens voltage of -50 V, a capillary temperature of 275 °C, a sheath flow rate of 30 L/min, and an auxiliary gas flow rate of 6 L/min. External calibration of mass spectra routinely produced a mass accuracy of better than 3 ppm. All FT mass spectra were acquired at a resolution 60 000 with 200-2000 Da mass range. **Conclusions:** All three products, Atabay enoxaparin, Lovenox, and Clexane had similar oligosaccharide maps. **Top-down analysis (intact chain analysis)** Introduction: LMWH is a poly-disperse mixture of oligosaccharide and polysaccharide chains of variable structure. Direct analysis of the intact chains in a LMWH can be performed using LC-MS can be used to provide the chain compositions of LMWH samples and used to assess their structural similarity. **Reagents:** Acetonitrile, ammonium acetate, and water were of HPLC grade. HILIC LC ESI-LTQ-Orbitrap-FT-MS Analysis of LMWH: A Luna HILIC column (2.0 × 150 mm2, 200 Å, Phenomenex, Torrance, CA) was used to separate the LMWHs. Mobile phase A was 5 mM ammonium acetate prepared with HPLC grade water. Mobile B was 5 mM ammonium acetate prepared in 98% HPLC grade acetonitrile with 2% of HPLC grade water. After injection of 8.0 µl LMWH (1.0 µg/µl) through an Agilent 1200 auto sampler, HPLC binary pump was used to deliver the gradient from 10% A to 35% A over 40 min at a flow rate of 150 µl/min. The LC column was directly connected online to the standard ESI source of LTQ-Orbitrap XL FT MS (Thermo Fisher Scientific, San Jose, CA). The source parameters for FT- MS detection were optimized using

		Arixtra to minimize the in- source fragmentation and sulfate loss and maximize the signal/ noise in the negative-ion mode. The optimized parameters, used to prevent in-source fragmentation, included a spray voltage of 4.2 kV, a capillary voltage of -40 V, a tube lens voltage of -50 V, a capillary temperature of 275 °C, a sheath flow rate of 30, and an auxiliary gas flow rate of 6. External calibration of mass spectra routinely produced a mass accuracy of better than 3 ppm. All FT mass spectra were acquired at a resolution 60 000 with 400-2000 Da mass range. **Conclusions:** All three products, Atabay enoxaparin, Lovenox, and Clexane had similar intact chain compositions.
4.	Equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	Anti-factor Xa & Anti-factor IIa activity by using USP reference standards.
5.	Equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	An open-label, randomized, single-dose, two-way, crossover pivotal bioequivalence study comparing Enox 10000 anti-Xa IU/ 1,0 ml Solution for injection in pre-filled syringes, Atabay Kimya San. Ve Tic. A.Ş., Turkey, containing enoxaparin sodium vs. CLEXANE 10.000 I.E.(100 mg)/1ml Injektionslösung in einer Fertigspritze, Sanofi Aventis Deutschland GmbH, Germany in healthy adult volunteers under fasting conditions
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the above stated products i.e., Enox 2000 Anti-XA IU/0.2 mL Pre-Filled Syringes, Enox 4000 Anti-XA IU/0.4 mL Pre-Filled Syringes, Enox 6000 Anti-XA IU/0.6 mL Pre-Filled Syringes and Enox 8000 Anti-XA IU/0.8 mL Pre-Filled Syringes subject to compliance of current Import Policy for finished drugs.		
7.	Name, address of Applicant / Importer	M/s AMB HK ENTERPRISES Pvt. Ltd, 2nd floor plaza 60, Commercial Block-K, Phase-1 DHA, Lahore.
	Details of Drug Sale License of importer	**License No**: 05-352-0058-104514D **Validity**: 08-05-2028 **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore **Status**: License to sell drugs by way of whole sale. **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Cisen Pharmaceutical Co., Ltd. Hai Chuan Road, Jining High &New Technology Industrial Development Zone, Shandong, P.R. China.
	Name, address of manufacturer(s)	M/s Cisen Pharmaceutical Co., Ltd. Hai Chuan Road, Jining High &New Technology Industrial Development Zone, Shandong, P.R. China.
	Name of exporting country	China

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (No. 20236074) dated 01-11-2022 issued Shandong Provincial Medical Products Administration for Enoxaparin Sodium, 0.4ml:4000IU injection. The CoPP confirms free sale status of the product in the exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 11-06-2025.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from **Cisen Pharmaceutical Co., Ltd**. The letter specifies that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 17335; Dated 11-07-2023
	Details of fee submitted	Rs. 150,000/- ; (Slip # 32678618)
	The proposed proprietary name / brand name	Enoparin Injection 0.4mL
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.4mL pre-filled syringe contains: Enoxaparin Sodium…..…...4000IU
	Dosage form of applied drug	Solution for Injection in PFS
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**.
	For generic drugs (me-too status)	Clexane® Syringes 4,000 IU (40 mg)/0.4 ml solution for injection in pre-filled syringe
	Module-II (Quality Overall Summary)	Firm has submitted ICH QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has

		also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Shandong Chenlong Pharmaceutical Co. LTD, Jinwei Road, Zhanghuang Industrial Zone, Zhanghuang, Yutai, Shandong, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25℃ ± 2℃. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	• Prefilled Syringes (with Stainless Steel Needles） • Assembling unit is composed of glass syringe, rubber plunger, stainless steel needle, needle cap and push rod.
	Stability study data of drug product	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40℃ ±2℃ / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 25℃ ±2℃ / 60% ± 5% RH for 24 months. 170516 170518 170520
	Non-clinical studies	The firm has submitted pre-clinical study reports of following: • Pharmacology • Pharmacokinetics Absorption Distribution Elimination
	Clinical studies	A monocentric, randomized, open-label, single-dose, two-period, crossover study to assess the pharmacokinetic and pharmacodynamic equivalence of Reference Clexane 6000 IU/0.6 mL solution for injection in prefilled syringe and test formulation of Enoxaparin 6000 IU/0.6ml following subcutaneous administration in healthy subjects in fasting conditions.

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
1.	Submit valid original legalized copy of CoPP issued by concerned regulatory authority of country of origin.	The firm has submitted original, legalized CoPP (No. 20236074) dated 01-11-2022 issued Shandong Provincial Medical Products Administration for Enoxaparin Sodium,0.4ml: 4000IU injection. The CoPP confirms free sale status of the product in the exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
2.	Submit details of letter of authorization / sole agency agreement for applied product.	Firm has submitted copy of letter of distribution certificate from **Cisen Pharmaceutical Co., Ltd**. The letter specifies that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan.
3.	You have mentioned Chinese pharmacopoeia specifications (3.2.P.5.1) while the product Enoxaparin sodium Injection is present in USP. Clarification is required.	The firm has revised the specifications to USP and requested to grant Registration as per USP specifications for the applied product. Accordingly, revised specifications and method of analysis have been submitted.

8.	**Name, address of Applicant / Importer**	**M/s AMB HK ENTERPRISES Pvt. Ltd,** 2nd floor plaza 60, Commercial Block-K, Phase-1 DHA, Lahore.
	Details of Drug Sale License of importer	**License No**: 05-352-0058-104514D **Validity**: 08-05-2028 **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore **Status**: License to sell drugs by way of whole sale. **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Cisen Pharmaceutical Co., Ltd. Hai Chuan Road, Jining High &New Technology Industrial Development Zone, Shandong, P.R. China.
	Name, address of manufacturer(s)	M/s Cisen Pharmaceutical Co., Ltd. Hai Chuan Road, Jining High &New Technology Industrial Development Zone, Shandong, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 20236073) dated 01-11-2022 issued Shandong Provincial Medical Products Administration for Enoxaparin Sodium, 0.6ml: 6000IU injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 11-06-2025.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from **Cisen Pharmaceutical Co., Ltd**. The letter specifies that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 17337; Dated 11-07-2023
	Details of fee submitted	Rs. 150,000/- ; (Slip # 644328143072)
	The proposed proprietary name / brand name	Enoparin injection 0.6mL
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.6mL pre-filled syringe contains: Enoxaparin Sodium…….6000IU
	Dosage form of applied drug	Solution for Injection in PFS
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**.
	For generic drugs (me-too status)	Clexane® Syringes 6,000 IU (60 mg)/0.6 mL solution for injection in pre-filled syringe
	Module-II (Quality Overall Summary)	Firm has submitted ICH QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Shandong Chenlong Pharmaceutical Co. LTD, Jinwei Road, Zhanghuang Industrial Zone, Zhanghuang, Yutai, Shandong, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time

		stability data is conducted at 25℃±2℃. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	• Prefilled Syringes （with Stainless Steel Needles） • Assembling unit is composed of glass syringe, rubber plunger, stainless steel needle, needle cap and push rod.
	Stability study data of drug product	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40℃ ± 2℃ / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 25℃ ± 2℃ / 60% ± 5% RH for 24 months. 170524 170526 170528
	Non-Clinical studies	The firm has submitted pre-clinical study reports of following: • Pharmacology • Pharmacokinetics *Absorption* *Distribution* *Elimination*
	Clinical studies	A monocentric, randomized, open-label, single-dose, two-period, crossover study to assess the pharmacokinetic and pharmacodynamic equivalence of Reference Clexane 6000 IU/0.6 mL solution for injection in prefilled syringe and test formulation of Enoxaparin 6000 IU/0.6ml following subcutaneous administration in healthy subjects in fasting conditions.

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
1.	Submit valid original legalized copy of CoPP issued by concerned regulatory authority of country of origin.	The firm has submitted original, legalized CoPP (No. 20236073) dated 01-11-2022 issued Shandong Provincial Medical Products Administration for Enoxaparin Sodium, 0.6ml: 6000IU injection. The CoPP confirms free sale status of the product in the exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
2.	Submit details of letter of authorization / sole agency agreement for applied product.	Firm has submitted copy of letter of distribution certificate from **Cisen Pharmaceutical Co., Ltd**. The letter specifies that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan.

	3.	You have mentioned Chinese pharmacopoeia specifications (3.2.P.5.1) while the product Enoxaparin sodium Injection is present in USP. Clarification is required.	The firm has revised the specifications to USP and requested to grant Registration as per USP specifications for the applied product. Accordingly, revised specifications and method of analysis have been submitted.

Decision:

Data as per guidelines of 289th meeting of Registration Board;

For Finished Import:

Sr. No.	Required Documents	Documents Provided by the Firm
1.	Equivalence of physicochemical properties, such as: c. Molecular weight distribution using size exclusion chromatography. d. Chain mapping by cetyltrimethyl ammonium-coated strong anion exchange chromatography matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	The analysis method includes following studies: i. Proton nuclear magnetic resonance (1H-NMR) ii. 13C-NMR iii. COSY, HSQC, HMBC, NOESY, TOCSY iv. HPLC-ESI-MS v. TIC vi. EIC vii. UV, IR HPLC, LC (refractive index detector)
2.	Equivalence of heparin source material (i.e. heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (i.e. cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	Enoxaparin sodium is manufactured in three stages, starting from the heparin sodium which undergoes a step of salification to get the quaternary ammonium salt of heparin (Intermediate I). The salification step is followed by an esterification step to form the ester salt of heparin (Intermediate II). Enoxaparin sodium is finally isolated after depolymerization and purification steps.
3.	Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by following: g. Capillary Electrophoresis (CE) h. Reverse phase high-performance liquid chromatography (RP-HPLC) i. Strong anion exchange HPLC (SAX-HPLC) j. Mass spectroscopy	**I. Monosaccharide composition analysis** This project uses heteronuclear single quantum correlation two-dimensional nuclear magnetic resonance spectroscopy (2D-CH-HSQC-NMR) to identify various uronic acid structures and various substituted forms of glucosamine in enoxaparin sodium samples, as well as their characteristics and original terminal structures. The relative quantification of each monosaccharide composition is performed through signal intensity integration. The signal peaks of the reducing end I, 6-inner ether structure, non-reducing end unsaturated uronic acid, and various monosaccharide components in enoxaparin sodium can be detected in Original Drug Clexane injection (batches 9S360, 9S361, 9S397) and

	k. Nuclear magnetic resonance (NMR) spectroscopy. l. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.	enoxaparin sodium samples from Cisen Pharmaceutical Co., Ltd. (batches 5319110101, 5320020101; 5320030101), and the spectra are similar. There is no significant difference in the relative percentage content of characteristic monosaccharide components. **II. Disaccharides and basic building blocks** This project uses a mixture of heparanase I, II, and III enzymes to treat Original Drug Clexane injection (batches 9S360, 9S361, 9S397) and enoxaparin sodium samples from Cisen Pharmaceutical Co., Ltd. (batches 5319110101, 5320020101, 5320030101), and then the hydrolysates were qualitatively and quantitatively analyzed by the hydrophilic interaction liquid chromatography electrospray ionization mass spectrometry (HILIC-ESI-MS). The TIC spectra of disaccharides and basic components produced by complete enzymatic hydrolysis of Original Drug Clexane injection (batches 9S360, 9S361, 9S397) and enoxaparin sodium samples from Cisen Pharmaceutical Co., Ltd. (batches 5319110101, 5320020101, 5320030101) are basically consistent. Relative quantitative analysis was conducted on each component, and the disaccharides and basic components were found to be consistent with the Original Drug Clexane injection. **III. Oligosaccharide fragments** The purpose of this experiment is to degrade the original drug Clexane injection (batches 9S360, 9S361, 9S397) and enoxaparin sodium samples from Chenxin Pharmaceutical Co., Ltd. (batches 5319110101, 5320020101, 5320030101) using heparanase 1, II, and III, respectively, and analyze the resulting oligosaccharide fragments, Compare the homogeneity of oligosaccharide fragment distribution between Original Drug Clexane injection and Cisen Pharmaceutical Co., Ltd. enoxaparin sodium samples. Relative quantitative analysis was conducted on the oligosaccharides, including the end structure components, produced by the enzymatic hydrolysis of Original Drug Clexane injection (batches 9S360, 9S361, 9S397) and enoxaparin sodium samples from Cisen Pharmaceutical Co., Ltd. (batches 5319110101, 5320020101, 5320030101) using heparanase I, II, and III enzymes. The oligosaccharide composition units were basically consistent with the Original Drug Clexane injection.
4.	Equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-	i. Anti-factor Xa activity by using antithrombin (AT III) solution, factor Xa solution and Chromogenic substrate S- 2765. ii. Anti-factor IIa activity by using Antithrombin solution, Thrombin solution and chromogenic substrate S-2238.

	Xa/anti-IIa ratio between the generic LMWHs should be provided.	iii. The anticoagulant activity of the biosimilar enoxaparin drug product is analyzed and compared with Clexane® based on aPTT (Activated Partial Thromboplastin Time) and Heptest prolongation time.
5.	Equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	A monocentric, randomized, open-label, single-dose, two-period, crossover study to assess the pharmacokinetic and pharmacodynamic equivalence of Reference product Clexane 6000 IU/0.6 mL solution for injection in prefilled syringe and test formulation of Enoxaparin 6000 IU/0.6ml following subcutaneous administration in healthy subjects in fasting conditions.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the above stated products i.e. Enoparin Injection 0.4mL and Enoparin Injection 0.6mL subject to compliance of current Import Policy for finished drugs.		

Cases of Local manufacturing of Human Biological Product

Application of Bulk concentrate import, local formulation and filling by M/s Sami Pharmaceuticals, Karachi.

DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the relevant section PR-II/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 2nd June, 2023 informed that the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2020-2021** and submitted applications for priority consideration in lieu of export facilitation for Registration Board, please.

9.	**Name, address of Applicant / Importer**	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Details of Drug Sale License of importer	M/s SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Name and address of marketing authorization holder (abroad)	**Shenzhen Techdow Pharmaceutical Co., Ltd site** No.19, Gaoxinzhongyi Road, Nanshan District, Shenzhen, Guangdong Province, China.
	Name, address of manufacturer(s)	**Shenzhen Techdow Pharmaceutical Co., Ltd site** No.19, Gaoxinzhongyi Road, Nanshan District, Shenzhen, Guangdong Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. Guangdong 20210326) valid till 14-09-2023 issued by GUANGDONG MEDICAL PRODUCTS ADMINISTRATION legalized by China Council for the Promotion of International Trade (CCPIT). The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 24/01/2021

		along with Notice to Stakeholder by EMA of 2020, 2021 & 2022 for the extension of GMP till 2023.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No.16768 Dated 05-07-2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**DENORIN 4000 Anti-Xa IU/0.4mL Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled Syringe 4000 anti-Xa IU contain: Enoxaparin Sodium ……. 40mg/0.4mL
	Pharmaceutical form of applied drug	A clear, colorless to pale yellow sterile solution for injection
	Pharmacotherapeutic Group of (API)	Anticoagulant/Antithrombotic agent ATC: B01AB05
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per DPC
	Shelf Life	2 years
	Storage Condition	Store between 15-30ºC
	The status in reference regulatory authorities	Clexane® Syringes 4,000 IU (40 mg)/0.4 ml solution for injection in pre-filled syringes by Sanofi Aventis Pharma Limited, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK
	For generic drugs (me-too status)	Clexane 4000 anti-Xa IU/0.4ml Injectable Solution by M/s Sanofi Aventis, Reg. No. 017004
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug

		product is submitted.
	Name, address of drug substance manufacturer	**Shenzhen Techdow Pharmaceutical Co., Ltd site** No.19, Gaoxinzhongyi Road, Nanshan District, Shenzhen, Guangdong Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C, 75±5% RH for 36 months Accelerated: 40°C ± 2°C, 75±5% RH for 6 months Batches: (401116017, 401116018, 401116020).
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, and specificity for Enoxaparin Sodium (Anti-Factor IIa & Anti-Factor Xa).
	Container closure system of the drug product	The primary packaging is 1 mL 27G, Glass Barrel Pre-fillable Syringe and sterile Plunger Chlorobutyl stopper.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 40±2ºC/75% RH±5% for 6 months. The real time stability study data is conducted at 30±2ºC/75% RH ±5 for 6 months. Lab-01 Lab-02 Lab-03
Data as per guidelines of 289th meeting of Registration Board; **For Bulk Concentrate Import, Local formulation, Filling:**		
i.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Copy of GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 24/01/2021 along with Notice to Stakeholder by EMA of 2020, 2021 & 2022 for the extension of GMP till 2023
ii.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as	legalized CoPP certificate (No. Guangdong 20210326) valid till 14-09-2023 issued by GUANGDONG MEDICAL PRODUCTS ADMINISTRATION

<table>
<tr><td></td><td>adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.</td><td>legalized by China Council for the Promotion of International Trade (CCPIT).</td></tr>
<tr><td>iii.</td><td colspan="2">The firm shall provide the complete data as adopted for imported Enoxaparin injections in 289th meeting of Registration Board of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the similar efficacy and safety to innovator product covering following requirements:</td></tr>
<tr><td></td><td>a) The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethyl ammonium-coated strong anion exchange chromatography, matrix assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair electro spray ionization mass spectroscopy (RPIPESI-MS).</td><td>
<table>
<tr><td rowspan="12">Equivalence of physicochemincal properties</td><td>1. Weight average molecular mass and molecular mass distribution</td></tr>
<tr><td>2. Molecular mass (HP-SEC-TDA)</td></tr>
<tr><td>3. Chain mapping (RPIP-HPLC-MS)</td></tr>
<tr><td>4. Chain mapping (UPLC-SEC-MS)</td></tr>
<tr><td>5. ^{1}H-NMR、^{13}C-NMR、HSQC</td></tr>
<tr><td>6. Specific absorbance</td></tr>
<tr><td>7. UV absorption</td></tr>
<tr><td>8. Ratio of sulfate ions to carbonate ions</td></tr>
<tr><td>9. Nitrogen content</td></tr>
<tr><td>10. Sodium</td></tr>
<tr><td>11. Free sulfate</td></tr>
<tr><td>12. Benzyl alcohol</td></tr>
</table>
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<tr><td></td><td>b) The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.</td><td>The raw material (heparin sodium) of Enoxaparin sodium API is purchased from Shenzhen Hepalink Pharmaceutical Co., Ltd. The release COA from the supplier "Hepalink" and the in-house release COA from Techdow can prove that heparin sodium API comes from porcine intestinal mucosa and comply with the requirements of Ph. Eur. monograph.

Similarity study of disaccharide units in Enoxaparin sodium by the mixed heparinase and nitrous acid degradation method, The components obtained from mixed heparinase degradation method (SAX-HPLC) include the disaccharide units from heparin sodium material and modified disaccharide units due to manufacture process.</td></tr>
<tr><td></td><td>c) The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide</td><td>
<table>
<tr><td rowspan="3">Equivalence in disaccharide building blocks</td><td>1. 1, 6-anhydro derivatives</td></tr>
<tr><td>2. Disaccharide building blocks degraded with heparinase using SAX-HPLC</td></tr>
<tr><td>3. Disaccharide building blocks degraded with nitrous acid using SAX-HPLC</td></tr>
</table>
Enoxaparin sodium is digested by heparinase I, II, III respectively during this study, and then analyze the oligosaccharide fragments obtained by RPIP-UPLC-ESI-MS method</td></tr>
</table>

	building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg. 2-0-sulfatase, 6-0-sulfatase, and 5glucuronidase) can be included.	Isolate enoxaparin sodium by GPC to obtain tetrasccharide. Determine the sequence information of tetrasccharide. By combined analysis of MS and NMR, the sequence information of tetrasccharide was obtained <table><tr><td rowspan="3">Equivalence in oligosaccharide fragment mapping</td><td>1. Oligosaccharide fragment (degraded with heparinase I) mapping using RPIP-HPLC-MS</td></tr><tr><td>2. Oligosaccharide fragment (degraded with heparinase II) mapping using RPIP-HPLC-MS</td></tr><tr><td>3. Oligosaccharide fragment (degraded with heparinase III) mapping using RPIP-HPLC-MS</td></tr></table>
	d) The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	In-vitro Bioequivalence study of Low molecular weight Heparins for comparison of the product on aPTT & FXa activity with that of reference drug by aPTT assay & Anti-FXa assay.
	e) The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti- Xa and anti-IIa profiles.	A randomised, open-label, single-dose, 2-waycross-over comparative pk/pd study of biosimilar enoxaparin sodium 40 vs. Reference medicinal product clexane after subcutaneous administration in healthy volunteers under fasting conditions.
iv.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	NA
v.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	36 months real time stability study data at 30°C±2°C, 75%RH±5% RH & 6 months accelerated stability study at 40°C±2°C, 75% RH ±5% RH of drug substance from API manufacturer.
vi.	The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.	1. Identification by Size-Exclusion Chromatography (GPC) 2. Anti-Factor Xa Activity Chromogenic assay 3. Anti-Factor Ila activity Chromogenic assay 4. Color & clarity of solution 5. Light Absorption 6. Sodium by Atomic Absorption Spectrophotometry 7. Related Substances by HPLC

vii.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months' stability data on all the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.	The accelerated stability study data is conducted at 40 ºC ±2ºC/75% RH±5% for 6 months. The real time stability study data is conducted at 30±2ºC/75% RH ±5 for 6 months.
viii.	The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used: a. SDS-PAGE for individual proteins 1. GC-MS for lipid impurities 2. Threshold ® Total DNA Assay System for DNA content.	Related Substances by HPLC: Purity of LMW heparins by using Anion Exchange Chromatography based test. Sodium by Atomic Absorption Spectrophotometry.
ix.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Submitted
x.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Submitted
xi.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Submitted
xii.	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Submitted
xiii.	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Submitted

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the above stated products i.e. DENORIN 4000 Anti-Xa IU/0.4mL Injection subject to compliance of current Import Policy for finished drugs.		
10.	**Name, address of Applicant / Importer**	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd**. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Details of Drug Sale License of importer	M/s SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Name and address of marketing authorization holder (abroad)	**Shenzhen Techdow Pharmaceutical Co., Ltd site** No.19, Gaoxinzhongyi Road, Nanshan District, Shenzhen, Guangdong Province, China
	Name, address of manufacturer(s)	**Shenzhen Techdow Pharmaceutical Co., Ltd site** No.19, Gaoxinzhongyi Road, Nanshan District, Shenzhen, Guangdong Province, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. Guangdong 20210326) valid till 14-09-2023 issued by GUANGDONG MEDICAL PRODUCTS ADMINISTRATION legalized by China Council for the Promotion of International Trade (CCPIT). The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 24/01/2021 along with Notice to Stakeholder by EMA of 2020, 2021 & 2022 for the extension of GMP till 2023
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No.16667 Dated 05-07-2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**DENORIN 6000 Anti-Xa IU/0.6mL Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled Syringe (0.6mL) contain: Enoxaparin Sodium ……. 60mg
	Pharmaceutical form of applied drug	A clear, colorless to pale yellow sterile solution for injection
	Pharmacotherapeutic Group of (API)	Anticoagulant/Antithrombotic agent ATC: B01AB05
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per DPC
	Shelf Life	2 years
	Storage Condition	Store between 15°C -30°C
	The status in reference regulatory authorities	Clexane® Syringes 6,000 IU (60 mg)/0.6 ml solution for injection in pre-filled syringes by Sanofi Aventis Pharma Limited, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK
	For generic drugs (me-too status)	Clexane 6000 anti-Xa IU/0.6ml Injectable Solution by M/s Sanofi Aventis, Reg. No. 017809
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	**Shenzhen Techdow Pharmaceutical Co., Ltd site** No.19, Gaoxinzhongyi Road, Nanshan District, Shenzhen, Guangdong Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ±2°C, 75%±5% RH for 36 months Accelerated: 40°C ±2°C, 75% ± 5% RH for 6 months Batches: (401116017, 401116018, 401116020).
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, and specificity for Enoxaparin Sodium (Anti-Factor IIa & Anti-Factor Xa).
	Container closure system of the drug product	The primary packaging is 1 mL 27G, Glass Barrel Prefillable Syringe and sterile Plunger Chlorobutyl stopper.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 40°C ±2°C/75% RH±5% for 6 months. The real time stability study data is conducted at 30°C ±2°C /75% RH ±5 for 6 months. Lab-01 Lab-02 Lab-03
Data as per guidelines of 289th meeting of Registration Board; **For Bulk Concentrate Import, Local formulation Filling:**		
i.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Copy of GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 24/01/2021 along with Notice to Stakeholder by EMA of 2020, 2021 & 2022 for the extension of GMP till 2023
ii.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	legalized CoPP certificate (No. Guangdong 20210326) valid till 14-09-2023 issued by GUANGDONG MEDICAL PRODUCTS ADMINISTRATION legalized by China Council for the Promotion of International Trade (CCPIT).
iii.	The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the similar efficacy and safety to innovator product covering following requirements:	

a) The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair electro spray ionization mass spectroscopy (RPIPESI-MS).

Equivalence of physicochemincal properties	1. Weight average molecular mass and molecular mass distribution
	2. Molecular mass (HP-SEC-TDA)
	3. Chain mapping (RPIP-HPLC-MS)
	4. Chain mapping (UPLC-SEC-MS)
	5. ^{1}H-NMR、^{13}C-NMR、HSQC
	6. Specific absorbance
	7. UV absorption
	8. Ratio of sulfate ions to carbonate ions
	9. Nitrogen content
	10. Sodium
	11. Free sulfate
	12. Benzyl alcohol

b) The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (i.e., heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.

The raw material (heparin sodium) of Enoxaparin sodium API is purchased from Shenzhen Hepalink Pharmaceutical Co., Ltd. The release COA from the supplier "Hepalink" and the in-house release COA from Techdow can prove that heparin sodium API comes from porcine intestinal mucosa and comply with the requirements of Ph. Eur. monograph.

Similarity study of disaccharide units in Enoxaparin sodium by the mixed heparinase and nitrous acid degradation method, The components obtained from mixed heparinase degradation method (SAX-HPLC) include the disaccharide units from heparin sodium material and modified disaccharide units due to manufacture process.

c) The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR)

Equivalence in disaccharide building blocks	1. 1, 6-anhydro derivatives
	2. Disaccharide building blocks degraded with heparinase using SAX-HPLC
	3. Disaccharide building blocks degraded with nitrous acid using SAX-HPLC

Enoxaparin sodium is digested by heparinase I, II, III respectively during this study, and then analyze the oligosaccharide fragments obtained by RPIP-UPLC-ESI-MS method

Isolate enoxaparin sodium by GPC to obtain tetrasccharide. Determine the sequence information of tetrasccharide. By combined analysis of MS and NMR, the sequence information of tetrasccharide was obtained

Equivalence in oligosaccharide fragment mapping	1. Oligosaccharide fragment (degraded with heparinase I) mapping using RPIP-HPLC-MS
	2. Oligosaccharide fragment (degraded with heparinase II) mapping using RPIP-HPLC-MS
	3. Oligosaccharide fragment (degraded with heparinase III) mapping using RPIP-HPLC-MS

	spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg. 2-0-sulfatase, 6-0-sulfatase, and 5glucuronidase) can be included.	
	d) The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	In-vitro Bioequivalence study of Low molecular weight Heparins for comparison of the product on aPTT & FXa activity with that of reference drug by aPTT assay & Anti-FXa assay.
	e) The fifth criterion for establishing sameness of enoxaparin is equivalence of ex-vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	A randomised, open-label, single-dose, 2-waycross-over comparative pk/pd study of biosimilar enoxaparin sodium 40 vs. Reference medicinal product clexane after subcutaneous administration in healthy volunteers under fasting conditions.
iv.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	NA
v.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance	36 months real time stability study data at 30°C±2°C, 75%RH±5% RH & 6 months accelerated stability study at 40°C±2°C, 75% RH ±5% RH of drug substance from API manufacturer.
vi.	The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.	1. Identification by Size-Exclusion Chromatography (GPC) 2. Anti-Factor Xa Activity Chromogenic assay 3. Anti-Factor IIa activity Chromogenic assay 4. Color & clarity of solution 5. Light Absorption 6. Sodium by Atomic Absorption Spectrophotometry 7. Related Substances by HPLC
vii.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months' stability data on all the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.	The accelerated stability study data is conducted at 40±2ºC/75% RH±5% for 6 months. The real time stability study data is conducted at 30±2ºC/75% RH ±5 for 6 months.
viii.	The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total	Related Substances by HPLC: Purity of LMW heparins by using Anion Exchange Chromatography based test. Sodium by Atomic Absorption Spectrophotometry

	proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used: a. SDS-PAGE for individual proteins 3. GC-MS for lipid impurities 4. Threshold ® Total DNA Assay System for DNA content.	
ix.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Submitted
x.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Submitted
xi.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Submitted
xii.	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Submitted
xiii.	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Submitted
Remarks of Evaluator: • The firm has provided Biological products (rDNA Protein products, Heparins, Monoclonal antibodies) Section. • The CoPP provided the firm has been verified online but instead of the finished product only API Enoxapari Sodiun is mentioned.		
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the above stated products i.e. DENORIN 6000 Anti-Xa IU/0.6mL Injection subject to compliance of current Import Policy for finished drugs.		

Application of Finished Product, Local Manufacturing by M/s BF Biosciences Ltd, Raiwind, Lahore

DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the firm has achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2022-2023** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board.

Molecule: Semaglutide

Evaluator: Mr. Muhammad Kashif

11.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind , Lahore-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000655 Address: 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan Evidence of section: Parenterals (Liquid & Lyophilized) For Biologicals GMP: Last GMP conducted on 13-09-2023 valid up to 13-09-2025
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Manufacturing
	Dy. No. and Date of submission	Dy.No. 17970 (R&I) dated 17th July, 2023
	Details of fee submitted	PKR.30,000/- (Slip # 11115303395)
	The proposed proprietary name / brand name	**Sematide 0.25mg/0.188mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.188mL contains Semaglutide 0.25mg
	Pharmaceutical form of applied drug	Solution for Injection in PFS (For Subcutaneous use only)
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	In-House Specifications
	Proposed Pack size	1's (PFS)
	Proposed unit price	As per SRO
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 °C – 8 °C)

	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Zhejiang Peptides Biotech Co., Ltd No.8 Hengyizhi Road, Sanjie Town, Shengzhou City, Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **i) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	MP No. 223306B0/002018 Issue Dated: 16th August,2018 rm has submitted the GMP issued by People's Republic of China, China National Association of Pharmaceutical and Medical Equipment's Industry Technical Market

	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	rm has submitted that Issuance of FSC/COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. maglutide has been exported by DS Manufacturer to Bangladesh to Aristo Pharma & Incepta Pharma
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of drug substance of following 3 batches at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: ZG06210301 (mfg date; 13-03-2021) Batch No: ZG06210302 (mfg date; 28-03-2021) Batch No: ZG06210303 (mfg date; 13-04-2021)
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Applicable because of API import.
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.

<table>
<tr><td></td><td>reporting procedure shall be followed.</td><td></td></tr>
<tr><td></td><td>The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.</td><td>Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.</td><td>Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.</td><td>Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted details of analytical method validation.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>(PFS) 1mL USP Type 1 clear glass barrel, accompanied with Rubber plunger</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP</td><td>The firm has submitted copy of GD dated 31-10-2022 Form 6 dated 29-Sep 2022, commercial Invoice dated 16-09-2022 , Form 3 dated 16-09-2022 and Form 7 dated 16-09-2022 specifying the import of 9gram of semaglutide and Relevant Impurities 25mg each(working standard 100mg total).</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6months.
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Manufacturing date</th></tr>
<tr><td>020D03</td><td>680 PFS</td><td>March-2023</td></tr>
<tr><td>020D04</td><td>680 PFS</td><td>March-2023</td></tr>
<tr><td>020D05</td><td>680 PFS</td><td>March-2023</td></tr>
</table></td></tr>
<tr><td></td><td>Module IV</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td>Module V</td><td>Detailed in sameness evaluation mentioned below</td></tr>
</table>

	The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:
Biosimilarity parameters	**Sameness evaluation Data Submitted by M/s BF Biosciences Ltd**
Quality Comparison **1.** Physicochemical Characterization	Sematide Injection has been compared with **Ozempic inj.** Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. A. Primary sequence and physicochemical properties B. Secondary structure C. Oligomer/aggregation states D. Biological activities (by *in-vitro* or animal studies) **Sameness studies** **1. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Sematide with RLD. **Drug Substance** **Zhejiang Peptites Biotech Co. Ltd v/s OZEMPIC INJECTION** Comparative Testing with Ozempic Injection (3.2.S.3.2 P 16 - 38) i) Peptide Sequence analysis by mass spectrometer (Primary Structure). ii) Circular dichroism spectrum analysis (Secondary structure). iii) Isoelectric point by Imaging capillary isoelectric focusing electrophoresis (Secondary structure). iv) Related substances/ Impurities by RP HPLC**.** v) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. vi) Biological activities (Cell line HEK - 293). vii) Thermo analysis by Differential Scanning Calorimeter (DSC) method. In addition to above Following tests were performed on the **API (Semaglutide)**: **Primary Structure** i) Molecular Weight by Mass Spectrometry (3.2.S.3.1 - P. 18 - 19) ii) Amino Acid Analysis (3.2.S.3.1 - P. 6) ***Secondary Structure*** i) IR Spectrum (3.2.S.3.1 - P. 3) ii) UV Absorption (3.2.S.3.1 – P 4) iii) X-ray diffraction analysis (3.2.S.3.1 – P 14) iv) Thermogravimetric analysis (3.2.S.3.1 – P 15) **Drug Product** **Sematide Injection (Manufactured by: BF Biosciences)** ➢ Following tests were performed by BF Biosciences to **compare Finished product with Ozempic Injection:** **1. Primary Structure:** I) Complete peptide sequence Analysis by Mass Spectrometry. II) Peptide Mapping. **2. Secondary Structure:** I) Fourier Transform Infrared Spectrum. II) UV-Visible Spectrophotometer. **3. Physiochemical Test:**

	i) Appearance ii) Phenol content by RP HPLC. iii) pH. **4. Identification:** i) Identification by RP HPLC. ii) Molecular weight determination by SDS-PAGE. iii) Isoelectric point by IEF (Isoelectric Focusing). **5. Purity:** i) Subvisible Particles by Liquid Particle Counter. ii) Related Substances I by Reverse Phase HPLC. iii) Related Substances II by Reverse Phase HPLC. iv) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. **6. Assay Testing:** i) Assay by Reverse Phase HPLC **7. Biological Activity and Determination of Protein Content:** i) Determination of specific activity by in-vitro Bioassay and protein content determination by cAMP Hunter Bioassay Kit **8. Toxicity Testing:** i) Mammalian Erythrocytes Micronucleus Test **2. Quality**: ▪ *Chiral Analysis/Optical Rotation (3.2.S.3.1 – P 18)* ▪ *Elemental Analysis (3.2.S.3.2 – P 8)* ▪ *Capillary Isoelectric focusing (3.2.S.3.1 - P 10)* ▪ *Physicochemical properties (3.2.S.3.1 - P 17)* ▪ *Hygroscopicity (3.2.S.3.1 - P 17)* ▪ *Identification by RP HPLC (3.2.S.4.1 P 1)* ▪ *Related Substances by RP HPLC (3.2.S.4.1 P 2)* ▪ *Peptide content and assay by HPLC (3.2.S.4.1 P 2)* ▪ *Determination of higher molecular weights proteins by size exclusion chromatography/Polymer test by SEC(3.2.S.4.1 P 2)*
Biological Activity	**Biological bioactivity** <u>Animal studies (Mutagenicity testing):</u> Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats(Mammalian Erythrocytes Micronucleus Test) *Drug Substance Specifications* ▪ Physical Appearance ▪ Solubility ▪ Identification by RP HPLC ▪ Identification Molecular Weight Mass Spectrometry ▪ pH ▪ Water Content ▪ Clarity of Solution ▪ Amino Acid Analysis ▪ Sodium Ion ▪ Carbonate Ion ▪ Acetic Acid ▪ Trifluoroacetic acid ▪ Assay (RP HPLC)

	▪ Related Substances I by RP HPLC ▪ Related Substances I by RP HPLC ▪ Polymer by SEC ▪ Residual Solvents ▪ BET ▪ Total Aerobic microbial count ▪ Total Yeast & mould count ▪ Escherichia coli
Immunochemical properties	
Impurities	Impurity Profiles **Impurities profile** ▪ Peptide related Impurities Related Substances I & II (3.2.S.4.1 P 2) ▪ High molecular weight protein impurities (Polymers 3.2.S.4.1 P 2) ▪ Process related Impurities (3.2.S.3.2 – P 1) ▪ Intermediate residue and reaction by products (Restricted Part 3.2.S.2.4 P 1) ▪ Inorganic and Ion impurities (3.2.S.3.2 – P 8) ▪ Residual Solvents (3.2.S.3.2 – P 12) ▪ Elemental Impurities (3.2.S.3.2 – P 8) ▪ Genotoxic Impurity (3.2.S.3.2 – P 15) ▪ Nitrosamine Impurities (3.2.S.3.2 – P 36)
Stability Studies	The firm has submitted stability studies.
Non-Clinical studies	The firm has submitted invitro and in vitro studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test)
Clinical Studies	Not submitted as not required as per FDA Docket No. FDA-2017-P-6029, for which the firm has shared link on which online it can be verified. **Link:https://www.fdanews.com/ext/resources/files/2018/01-08-18-NovoNordisk.pdf?1520855365 .**
	The firm has submitted link from which it can be verified that according to the FDA, below will be considered as biologicals; 1. Therapeutic DNA plasmid products 2. **Therapeutic synthetic peptide products of 40 or fewer amino acids.** 3. Monoclonal antibody products for in vivo use. 4. Therapeutic recombinant DNA-derived products. Reference: Code of federal regulations, Title 21, Volume 7, CITE: 21CFR601.2 Link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=601.2
Deliberations of the board:	**CONCLUSION & RECOMMENDATIONS OF THE**

	COMMITTEE: of working group for deliberation regarding semaglutide is reproduced as under: The committee thoroughly reviewed the matter, considered the point of view and documents submitted by PPMA and Pharma Bureau, and the recommendations from the representative from Division of Biological Evaluation & Research. The committee observed that following important points: **1**. Semaglutide is a drug product produced using recombinant DNA technology in yeast (Saccharomyces cerevisiae) as evident from the assessment reports of European Medicine Agency as well as Food and Drug Administration. **2.** The definition of Biologicals under Schedule-I of DRAP Act, 2012 which specifies that *biotechnology products which are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques*, does not support the stance of PPMA regarding the number of amino acids as per USFDA definition, for dealing semaglutide product as pharmaceuticals. **3.** The innovator's product is manufactured in a dedicated facility for manufacturing of Biological products. **4.** Manufacturing of Biological products requires dedicated and self-contained facilities as per clause 5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976, under the Drugs Act, 1976. **5.** For approval of Biological products, it is essential that similarity has been thoroughly investigated and backed up with sufficient data to make the bridging to the reference product acceptable. **6.** Registration Board has already approved Semaglutide in Injectable and Tablet dosage form for the innovator product "Ozempic® Dual Dose" and "Rybelsus Tablet" of M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark in 293rd and 308th meeting as a biological drug product respectively. Based upon the above stated points, the committee recommends that Semaglutide shall be considered as a biological drug product for local use as well as for export, and be dealt by the Division of Biological Evaluation & Research. The manufacturing of this product shall be performed in dedicated and self- contained facilities for Biological drugs as per clause 5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Registration Board in its 331st meeting decided regarding local manufacturing of semaglutide injection as follows: **Decision of 331st DRB meeting:** **"*On the basis of documents/information/data along with sameness evaluation data as per FDA criteria and comparative testing with innovator product (Ozempic 2mg/1.5ml PFS of Novo Nordisk A/S), Registration Board approved the registration of Seglutide 2mg/1.5ml vial.***

		***The firm shall submit the non-clinical and clinical data of semaglutide finished product developed from same biological substance manufacturer i.e., Livzon.*"** Registration Board decided that an Expert Working Group may be constituted for semaglutide in which representative from PPMA also requested that they must be added in the said group.
Decision: Registration Board decided to refer the case to Expert Working Group for Semaglutide. The case will be decided in the light of recommendations of the Expert Working Group.		
12.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind , Lahore-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000655 Address: 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan Evidence of section: Parenterals (Liquid & Lyophilized) For Biologicals & Non-Biologicals GMP: Last GMP conducted on 13-09-2023 valid up to 13-09-2025
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Manufacturing
	Dy. No. and Date of submission	Dy.No. 17971 (R&I) dated 17th July, 2023
	Details of fee submitted	PKR.30,000/- (Slip # 544248872559)
	The proposed proprietary name / brand name	**Sematide 0.5mg/0.375 mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.375mL contains Semaglutide 0.5mg
	Pharmaceutical form of applied drug	Solution for Injection in PFS (For Subcutaneous use only)
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	In-House Specifications
	Proposed Pack size	1's (PFS)
	Proposed unit price	As per SRO

	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 °C – 8 °C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Zhejiang Peptides Biotech Co., Ltd No.8 Hengyizhi Road, Sanjie Town, Shengzhou City, Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **ii) For Bulk Concentrate Import/Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	MP No. 223306B0/002018 Issue Dated: 16th August,2018 rm has submitted the GMP issued by People's Republic of China, China National Association of Pharmaceutical and Medical Equipment's Industry Technical Market

	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	rm has submitted that Issuance of FSC/COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. maglutide has been exported by DS Manufacturer to Bangladesh to Aristo Pharma & Incepta Pharma
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of drug substance at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: ZG06210301 (mfg date; 13-03-2021) Batch No: ZG06210302 (mfg date; 28-03-2021) Batch No: ZG06210303 (mfg date; 13-04-2021)
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Applicable because of API import.
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.

<table>
<tr><td></td><td>reporting procedure shall be followed.</td><td></td></tr>
<tr><td></td><td>The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.</td><td>Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.</td><td>Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.</td><td>Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted details of analytical method validation.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>(PFS) 1mL USP Type 1 clear glass barrel, accompanied with Rubber plunger</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP</td><td>The firm has submitted copy of GD dated 31-10-2022 Form 6 dated 29-Sep 2022, commercial Invoice dated 16-09-2022 , Form 3 dated 16-09-2022 and Form 7 dated 16-09-2022 specifying the import of 9gram of semaglutide and Relevant Impurities 25mg each(working standard 100mg total).</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>Firm has submitted stability study data of following 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time ongoing stability study data is conducted at 5°C±3°C for 6 months.
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Manufacturing date</th></tr>
<tr><td>021D03</td><td>402 PFS</td><td>March-2023</td></tr>
<tr><td>021D04</td><td>402 PFS</td><td>March-2023</td></tr>
<tr><td>021D05</td><td>402 PFS</td><td>March-2023</td></tr>
</table></td></tr>
<tr><td></td><td>Module IV</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td>Module V</td><td>Detailed in sameness evaluation mentioned below</td></tr>
</table>

	The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:
Biosimilarity parameters	**Sameness evaluation Data Submitted by M/s BF Biosciences Ltd**
Quality Comparison **2.** Physicochemical Characterization	Sematide Injection has been compared with **Ozempic inj.** Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. E. Primary sequence and physicochemical properties F. Secondary structure G. Oligomer/aggregation states H. Biological activities (by *in-vitro* or animal studies) **Sameness studies** **3. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Sematide with RLD. **Drug Substance** **<u>Zhejiang Peptites Biotech Co. Ltd v/s OZEMPIC INJECTION</u>** Comparative Testing with Ozempic Injection (3.2.S.3.2 P 16 - 38) viii) Peptide Sequence analysis by mass spectrometer (Primary Structure). ix) Circular dichroism spectrum analysis (Secondary structure). x) Isoelectric point by Imaging capillary isoelectric focusing electrophoresis (Secondary structure). xi) Related substances/ Impurities by RP HPLC**.** xii) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. xiii) Biological activities (Cell line HEK - 293). xiv) Thermo analysis by Differential Scanning Calorimeter (DSC) method. In addition to above Following tests were performed on the **API (Semaglutide)**: **Primary Structure** iii) Molecular Weight by Mass Spectrometry (3.2.S.3.1 - P. 18 - 19) iv) Amino Acid Analysis (3.2.S.3.1 - P. 6) ***Secondary Structure*** v) IR Spectrum (3.2.S.3.1 - P. 3) vi) UV Absorption (3.2.S.3.1 – P 4) vii) X-ray diffraction analysis (3.2.S.3.1 – P 14) viii) Thermogravimetric analysis (3.2.S.3.1 – P 15) **Drug Product** **<u>Sematide Injection (Manufactured by: BF Biosciences)</u>** ➢ Following tests were performed by BF Biosciences to **compare Finished product with Ozempic Injection:** **9. Primary Structure:** III) Complete peptide sequence Analysis by Mass Spectrometry. IV) Peptide Mapping. **10. Secondary Structure:** III) Fourier Transform Infrared Spectrum. IV) UV-Visible Spectrophotometer. **11. Physiochemical Test:** iv) Appearance

	v) Phenol content by RP HPLC. vi) pH. **12. Identification:** iv) Identification by RP HPLC. v) Molecular weight determination by SDS-PAGE. vi) Isoelectric point by IEF (Isoelectric Focusing). **13. Purity:** v) Subvisible Particles by Liquid Particle Counter. vi) Related Substances I by Reverse Phase HPLC. vii) Related Substances II by Reverse Phase HPLC. viii) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. **14. Assay Testing:** ii) Assay by Reverse Phase HPLC **15. Biological Activity and Determination of Protein Content:** ii) Determination of specific activity by in-vitro Bioassay and protein content determination by cAMP Hunter Bioassay Kit **16. Toxicity Testing:** ii) Mammalian Erythrocytes Micronucleus Test **4. Quality**: ▪ *Chiral Analysis/Optical Rotation (3.2.S.3.1 – P 18)* ▪ *Elemental Analysis (3.2.S.3.2 – P 8)* ▪ *Capillary Isoelectric focusing (3.2.S.3.1 - P 10)* ▪ *Physicochemical properties (3.2.S.3.1 - P 17)* ▪ *Hygroscopicity (3.2.S.3.1 - P 17)* ▪ *Identification by RP HPLC (3.2.S.4.1 P 1)* ▪ *Related Substances by RP HPLC (3.2.S.4.1 P 2)* ▪ *Peptide content and assay by HPLC (3.2.S.4.1 P 2)* ▪ *Determination of higher molecular weights proteins by size exclusion chromatography/Polymer test by SEC(3.2.S.4.1 P 2)*
Biological Activity	**Biological bioactivity** <u>Animal studies (Mutagenicity testing):</u> Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test) *Drug Substance Specifications* ▪ Physical Appearance ▪ Solubility ▪ Identification by RP HPLC ▪ Identification Molecular Weight Mass Spectrometry ▪ pH ▪ Water Content ▪ Clarity of Solution ▪ Amino Acid Analysis ▪ Sodium Ion ▪ Carbonate Ion ▪ Acetic Acid ▪ Trifluoroacetic acid ▪ Assay (RP HPLC) ▪ Related Substances I by RP HPLC

	▪ Related Substances I by RP HPLC ▪ Polymer by SEC ▪ Residual Solvents ▪ BET ▪ Total Aerobic microbial count ▪ Total Yeast & mould count ▪ Escherichia coli
Immunochemical properties	
Impurities	Impurity Profiles **Impurities profile** ▪ Peptide related Impurities Related Substances I & II (3.2.S.4.1 P 2) ▪ High molecular weight protein impurities (Polymers 3.2.S.4.1 P 2) ▪ Process related Impurities (3.2.S.3.2 – P 1) ▪ Intermediate residue and reaction by products (Restricted Part 3.2.S.2.4 P 1) ▪ Inorganic and Ion impurities (3.2.S.3.2 – P 8) ▪ Residual Solvents (3.2.S.3.2 – P 12) ▪ Elemental Impurities (3.2.S.3.2 – P 8) ▪ Genotoxic Impurity (3.2.S.3.2 – P 15) ▪ Nitrosamine Impurities (3.2.S.3.2 – P 36)
Stability Studies	The firm has submitted stability studies.
Non-Clinical studies	The firm has submitted invitro and in vitro studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test)
Clinical Studies	Not submitted as not required as per FDA Docket No. FDA-2017-P-6029, for which the firm has shared link on which online it can be verified. **Link:https://www.fdanews.com/ext/resources/files/2018/01-08-18-NovoNordisk.pdf?1520855365.**
	The firm has submitted link from which it can be verified that according to the FDA, below will be considered as biologicals; 1. Therapeutic DNA plasmid products 2. **Therapeutic synthetic peptide products of 40 or fewer amino acids.** 3. Monoclonal antibody products for in vivo use. 4. Therapeutic recombinant DNA-derived products. Reference: Code of federal regulations, Title 21, Volume 7, CITE: 21CFR601.2 Link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=601.2
Deliberations of the board:	**CONCLUSION & RECOMMENDATIONS OF THE COMMITTEE: of working group for deliberation regarding semaglutide is reproduced as under:**

	The committee thoroughly reviewed the matter, considered the point of view and documents submitted by PPMA and Pharma Bureau, and the recommendations from the representative from Division of Biological Evaluation & Research. The committee observed that following important points: **1**. Semaglutide is a drug product produced using recombinant DNA technology in yeast (Saccharomyces cerevisiae) as evident from the assessment reports of European Medicine Agency as well as Food and Drug Administration. **2.** The definition of Biologicals under Schedule-I of DRAP Act, 2012 which specifies that *biotechnology products which are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques*, does not support the stance of PPMA regarding the number of amino acids as per USFDA definition, for dealing semaglutide product as pharmaceuticals. **3.** The innovator's product is manufactured in a dedicated facility for manufacturing of Biological products. **4.** Manufacturing of Biological products requires dedicated and self-contained facilities as per clause 5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976, under the Drugs Act, 1976. **5.** For approval of Biological products, it is essential that similarity has been thoroughly investigated and backed up with sufficient data to make the bridging to the reference product acceptable. **6.** Registration Board has already approved Semaglutide in Injectable and Tablet dosage form for the innovator product "Ozempic® Dual Dose" and "Rybelsus Tablet" of M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark in 293rd and 308th meeting as a biological drug product respectively. Based upon the above stated points, the committee recommends that Semaglutide shall be considered as a biological drug product for local use as well as for export, and be dealt by the Division of Biological Evaluation & Research. The manufacturing of this product shall be performed in dedicated and self- contained facilities for Biological drugs as per clause 5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Registration Board in its 331st meeting decided regarding local manufacturing of semaglutide injection as follows: **Decision of 331st DRB meeting:** **"*On the basis of documents/information/data along with sameness evaluation data as per FDA criteria and comparative testing with innovator product (Ozempic 2mg/1.5ml PFS of Novo Nordisk A/S), Registration Board approved the registration of Seglutide 2mg/1.5ml vial.*** ***The firm shall submit the non-clinical and clinical data of semaglutide finished product developed from same biological substance manufacturer i.e., Livzon.*"**

		Registration Board decided that an Expert Working Group may be constituted for semaglutide in which representative from PPMA also requested that they must be added in the said group.
Decision: Registration Board decided to refer the case to Expert Working Group for Semaglutide. The case will be decided in the light of recommendations of the Expert Working Group.		
13.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind , Lahore-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000655 Address: 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan Evidence of section: Parentals (Liquid & Lyophilized) For Biologicals & Non-Biologicals GMP: Last GMP conducted on 13-09-2023 valid up to 13-09-2025
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Manufacturing
	Dy. No. and Date of submission	Dy.No. 17972 (R&I) dated 17th July, 2023
	Details of fee submitted	PKR.30,000/- (Slip # 582864826)
	The proposed proprietary name / brand name	**Sematide 1mg/0.75mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.75mL contains Semaglutide 1mg
	Pharmaceutical form of applied drug	Solution for Injection in PFS (For Subcutaneous use only)
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	In-House Specifications
	Proposed Pack size	1's (PFS)
	Proposed unit price	As per SRO
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 °C – 8 °C)

	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Zhejiang Peptides Biotech Co., Ltd No.8 Hengyizhi Road, Sanjie Town, Shengzhou City, Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **iii) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	MP Issue Dated: 16th August,2018 rm has submitted the GMP issued by People's Republic of China, China National Association of Pharmaceutical and Medical Equipment's Industry Technical Market

	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	rm has submitted that Issuance of FSC/COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. maglutide has been exported by DS Manufacturer to Bangladesh to Aristo Pharma & Incepta Pharma
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of drug substance at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: ZG06210301 (mfg date; 13-03-2021) Batch No: ZG06210302 (mfg date; 28-03-2021) Batch No: ZG06210303 (mfg date; 13-04-2021)
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Applicable
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.

<table>
<tr><td></td><td>reporting procedure shall be followed.</td><td></td></tr>
<tr><td></td><td>The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.</td><td>Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.</td><td>Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.</td><td>Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted details of analytical method validation.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>(PFS) 1mL USP Type 1 clear glass barrel, accompanied with Rubber plunger</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP</td><td>The firm has submitted copy of GD, Form 6, commercial Invoice , Form 3 and Form 7 specifying the import of 9gram of semaglutide and Relevant Impurities 25mg each.</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5°C±3°C for 6 months.
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Manufacturing date</th></tr>
<tr><td>022D03</td><td>270 PFS</td><td>March-2023</td></tr>
<tr><td>022D04</td><td>270 PFS</td><td>March-2023</td></tr>
<tr><td>022D05</td><td>270 PFS</td><td>March-2023</td></tr>
</table></td></tr>
<tr><td></td><td>Module IV</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td>Module V</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td colspan="2">The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:</td></tr>
<tr><td colspan="2">Biosimilarity parameters</td><td>Sameness evaluation Data Submitted by M/s BF Biosciences Ltd</td></tr>
</table>

Quality Comparison **3.** Physicochemical Characterization	Sematide Injection has been compared with **Ozempic inj.** Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. I. Primary sequence and physicochemical properties J. Secondary structure K. Oligomer/aggregation states L. Biological activities (by *in-vitro* or animal studies) **Sameness studies** **5. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Sematide with RLD. **Drug Substance** **Zhejiang Peptites Biotech Co. Ltd v/s OZEMPIC INJECTION** Comparative Testing with Ozempic Injection (3.2.S.3.2 P 16 - 38) xv) Peptide Sequence analysis by mass spectrometer (Primary Structure). xvi) Circular dichroism spectrum analysis (Secondary structure). xvii) Isoelectric point by Imaging capillary isoelectric focusing electrophoresis (Secondary structure). xviii) Related substances/ Impurities by RP HPLC**.** xix) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. xx) Biological activities (Cell line HEK - 293). xxi) Thermo analysis by Differential Scanning Calorimeter (DSC) method. In addition to above Following tests were performed on the **API (Semaglutide)**: **Primary Structure** v) Molecular Weight by Mass Spectrometry (3.2.S.3.1 - P. 18 - 19) vi) Amino Acid Analysis (3.2.S.3.1 - P. 6) ***Secondary Structure*** ix) IR Spectrum (3.2.S.3.1 - P. 3) x) UV Absorption (3.2.S.3.1 – P 4) xi) X-ray diffraction analysis (3.2.S.3.1 – P 14) xii) Thermogravimetric analysis (3.2.S.3.1 – P 15) **Drug Product** **Sematide Injection (Manufactured by: BF Biosciences)** ➢ Following tests were performed by BF Biosciences to **compare Finished product with Ozempic Injection:** **17. Primary Structure:** V) Complete peptide sequence Analysis by Mass Spectrometry. VI) Peptide Mapping. **18. Secondary Structure:** V) Fourier Transform Infrared Spectrum. VI) UV-Visible Spectrophotometer. **19. Physiochemical Test:** vii) Appearance viii) Phenol content by RP HPLC. ix) pH. **20. Identification:** vii) Identification by RP HPLC. viii) Molecular weight determination by SDS-PAGE. ix) Isoelectric point by IEF (Isoelectric Focusing). **21. Purity:** ix) Subvisible Particles by Liquid Particle Counter. x) Related Substances I by Reverse Phase HPLC.

	xi) Related Substances II by Reverse Phase HPLC. xii) Polymer (Oligomer/ Aggregates/ High Molecular Weight Proteins) by Size Exclusion Chromatography. **22. Assay Testing:** iii) Assay by Reverse Phase HPLC **23. Biological Activity and Determination of Protein Content:** iii) Determination of specific activity by in-vitro Bioassay and protein content determination by cAMP Hunter Bioassay Kit **24. Toxicity Testing:** iii) Mammalian Erythrocytes Micronucleus Test **6. Quality**: ▪ *Chiral Analysis/Optical Rotation (3.2.S.3.1 – P 18)* ▪ *Elemental Analysis (3.2.S.3.2 – P 8)* ▪ *Capillary Isoelectric focusing (3.2.S.3.1 - P 10)* ▪ *Physicochemical properties (3.2.S.3.1 - P 17)* ▪ *Hygroscopicity (3.2.S.3.1 - P 17)* ▪ *Identification by RP HPLC (3.2.S.4.1 P 1)* ▪ *Related Substances by RP HPLC (3.2.S.4.1 P 2)* ▪ *Peptide content and assay by HPLC (3.2.S.4.1 P 2)* ▪ *Determination of higher molecular weights proteins by size exclusion chromatography/Polymer test by SEC(3.2.S.4.1 P 2)*
Biological Activity	**Biological bioactivity** <u>Animal studies (Mutagenicity testing):</u> Development of structural alerts for the In vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats(Mammalian Erythrocytes Micronucleus Test) *Drug Substance Specifications* ▪ Physical Appearance ▪ Solubility ▪ Identification by RP HPLC ▪ Identification Molecular Weight Mass Spectrometry ▪ pH ▪ Water Content ▪ Clarity of Solution ▪ Amino Acid Analysis ▪ Sodium Ion ▪ Carbonate Ion ▪ Acetic Acid ▪ Trifluoroacetic acid ▪ Assay (RP HPLC) ▪ Related Substances I by RP HPLC ▪ Related Substances I by RP HPLC ▪ Polymer by SEC ▪ Residual Solvents ▪ BET ▪ Total Aerobic microbial count ▪ Total Yeast & mould count ▪ Escherichia coli
Immunochemical properties	
Impurities	<u>Impurity Profiles</u>

	Impurities profile ▪ Peptide related Impurities Related Substances I & II (3.2.S.4.1 P 2) ▪ High molecular weight protein impurities (Polymers 3.2.S.4.1 P 2) ▪ Process related Impurities (3.2.S.3.2 – P 1) ▪ Intermediate residue and reaction by products (Restricted Part 3.2.S.2.4 P 1) ▪ Inorganic and Ion impurities (3.2.S.3.2 – P 8) ▪ Residual Solvents (3.2.S.3.2 – P 12) ▪ Elemental Impurities (3.2.S.3.2 – P 8) ▪ Genotoxic Impurity (3.2.S.3.2 – P 15) ▪ Nitrosamine Impurities (3.2.S.3.2 – P 36)
Stability Studies	The firm has submitted stability studies.
Non-Clinical studies	The firm has submitted invitro and in vitro studies (Mutagenicity testing): Development of structural alerts for the in vivo micronucleus assay in rodents. ▪ Comparative specific Activity by Biological Assay and Protein content by cAMP Hunter Kit 95-0062Y2-00175 ▪ Comparative Toxicological Studies: in Rats (Mammalian Erythrocytes Micronucleus Test)
Clinical Studies	Not submitted as not required as per FDA Docket No. FDA-2017-P-6029, for which the firm has shared link on which online it can be verified. **Link:https://www.fdanews.com/ext/resources/files/2018/01-08-18-NovoNordisk.pdf?1520855365** .
	The firm has submitted link from which it can be verified that according to the FDA, below will be considered as biologicals; 1. Therapeutic DNA plasmid products 2. **Therapeutic synthetic peptide products of 40 or fewer amino acids.** 3. Monoclonal antibody products for in vivo use. 4. Therapeutic recombinant DNA-derived products. Reference: Code of federal regulations, Title 21, Volume 7, CITE: 21CFR601.2 Link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=601.2
Deliberations of the board:	**CONCLUSION & RECOMMENDATIONS OF THE COMMITTEE: of working group for deliberation regarding semaglutide is reproduced as under:** The committee thoroughly reviewed the matter, considered the point of view and documents submitted by PPMA and Pharma Bureau, and the recommendations from the representative from Division of Biological Evaluation & Research. The committee observed that following important points: **1**. Semaglutide is a drug product produced using recombinant DNA technology in yeast (Saccharomyces cerevisiae) as evident from the assessment reports of European Medicine Agency as well as Food and Drug Administration. **2.** The definition of Biologicals under Schedule-I of DRAP Act, 2012 which specifies that *biotechnology products which are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques*, does not support the

	stance of PPMA regarding the number of amino acids as per USFDA definition, for dealing semaglutide product as pharmaceuticals. **3.** The innovator's product is manufactured in a dedicated facility for manufacturing of Biological products. **4.** Manufacturing of Biological products requires dedicated and self-contained facilities as per clause 5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976, under the Drugs Act, 1976. **5.** For approval of Biological products, it is essential that similarity has been thoroughly investigated and backed up with sufficient data to make the bridging to the reference product acceptable. **6.** Registration Board has already approved Semaglutide in Injectable and Tablet dosage form for the innovator product "Ozempic® Dual Dose" and "Rybelsus Tablet" of M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark in 293rd and 308th meeting as a biological drug product respectively. Based upon the above stated points, the committee recommends that Semaglutide shall be considered as a biological drug product for local use as well as for export, and be dealt by the Division of Biological Evaluation & Research. The manufacturing of this product shall be performed in dedicated and self- contained facilities for Biological drugs as per clause 5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Registration Board in its 331st meeting decided regarding local manufacturing of semaglutide injection as follows: **Decision of 331st DRB meeting:** **"*On the basis of documents/information/data along with sameness evaluation data as per FDA criteria and comparative testing with innovator product (Ozempic 2mg/1.5ml PFS of Novo Nordisk A/S), Registration Board approved the registration of Seglutide 2mg/1.5ml vial.* *The firm shall submit the non-clinical and clinical data of semaglutide finished product developed from same biological substance manufacturer i.e., Livzon.*"** Registration Board decided that an Expert Working Group may be constituted for semaglutide in which representative from PPMA also requested that they must be added in the said group.
Decision: Registration Board decided to refer the case to Expert Working Group for Semaglutide. The case will be decided in the light of recommendations of the Expert Working Group.	

Molecule: Urofollitropin (Follicle Stimulating Hormone)
Evaluator: Ms. Haleema Shareef

14.	**Name, address of Applicant/Importer**	**M/s Bristol Mayer Biotech Pakistan** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt
	Details of Drug Sale License of importer	**License No:** 05-352-0068-109282D **Address:** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt **Address of Godown:** NA **Validity:** 18.10.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Sanzyme (P) Limited** Plot No. 8,Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name, address of manufacturer (s)	**Sanzyme (P) Limited**

		Plot No. 8,Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP , Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copy of CoPP (No. 4116237/TS/2023) issued by Drugs Control Administration Government of Telangana for **Endogen HP 75 IU** valid up to 08/03/2026. The CoPP states that the product is **on free sale in exporting country**. **Free Sale Certificate:** Firm has submitted original, legalized copy of Free Sale Certificate (L. Dis. No: 116385/TS/2023) dated 25/04/2023 issued by Drugs Control Administration Government of Telangana for **Endogen HP 75 IU** valid up to 23/04/2024. The Free Sale Certificate states that the product is **on free sale in exporting country.** **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (L. Dis No: 100098/TS/2023) dated 10/03/2023 issued by Drugs Control Administration Government of Telangana valid up to 08/03/2026.
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **Sanzyme (P) Ltd.** The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to register their products in Pakistan. The authorization letter is valid till 08h February, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging as for export purpose only
	Dy. No. and date of submission	Dy. No: 8818 Date of submission: 31-03-2023
	Details of fee submitted	Rs: 150,000 Slip number: 524674723100 Dated : 09-03-2023
	The proposed proprietary name/ brand name	**Endogen HP 75 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Highly Purified Urofollitropin for Injection (Follicle Stimulating Hormone) ….75 IU
	Pharmaceutical form of applied drug	Lyophilized powder for Injection (vial) packed along with 1 ml ampoule Sodium Chloride 0.9% w/v
	Pharmacotherapeutic Group of (API)	Gonadotrophins ATC code: G03G A04

	Reference to Finished product specifications	BP
	Proposed Pack size	1's (Lyophilized powder for Injection (vial) & Sodium Chloride 0.9% w/v)
	Proposed unit price	Rs. 3500/1's
	Shelf Life	3 years
	Storage Conditions	2°C to 8°C. It should not be allowed to freeze.
	The status in reference regulatory authorities	Swiss medic (Switzerland) Approved Fostimon75 IU by IBSA Institute Biochimique SA
	For generic drugs (me-too status)	**Reg. No:**039810 **Company Name:** Galaxy Pharma (Pvt) Ltd., Karachi **Brand Name:** Follimon Injection **Formulation:** Each vial contains: - Urofollitropin (FSH) 75 iu and isotonic sodium chloride injection for reconstitution 1ml. **Pack Size:**1's (vial & ampoule)
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Shanghai Techwell Biopharmaceutical Co., Ltd. Address: No. 4258, Jindu Road, Shanghai 201108, China Tel: +86-21-54427100 Fax: +86-21-54426560 Email: liyan@techwell-cn.com Website: http://www.techwell-cn.com
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability data is conducted at 2-8 °C for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product

	Container closure system of the drug product	**Glass Vial:** 2 ml USP Type I Clear glass vial with 13 mm mouth outer diameter **Rubber stoppers :**13mm slotted grey bromobutyl rubber stopper(Type-I),(RFU) **Flip off seals:**13mm Aluminium flip off seal **Accompanying Diluent :**2ml USP Type-I, Clear glass ampoules(OPC) for diluent
	Stability study data of drug product, shelf life andstorage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at Temperature at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted Temperature 5± 3°C for 36 months as per ICH guidelines.
	Module-IV Non-Clinical	Toxicology studies were performed. Single-dose toxicity4.2.3.1 and Repeat-dose toxicity4.2.3.2 data was presented.
	Module-V Clinical	5.3.5.1 Study Reports of Controlled clinical Studies Pertinent to the claimed Indication were presented on 174 subjects. Clinical Study Report (5.3.5.1)with title **"**A Prospective, Randomized, Open-label, Concurrent-controlled, Three arm Study to Compare the Clinical Efficacy and Tolerability of Different Follicle-stimulating Hormone (Endogen® HP, Sanzyme vs Fostimon®, IBSA) and Human Chorionic Gonadotropin (Pubergen® HP, Sanzyme vs Pregnyl®, MSD Ltd) Combinations in Women Undergoing In Vitro Fertilization". The data from this study showed that we can conclude that Endogen is comparable to Fostimon; and Pubergen is comparable to Pregnyl in terms of primary and secondary efficacy endpoints, and that no statistical significant difference was observed between the 3 treatment groups, thus indicating the non-inferiority of test products as compared to the reference products. Under 5.3.6 Reports of post marketing experience, Periodic safety update report is also presented from 01st January 2021 to 31st December 2021.
Remarks of Evaluator		
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
15.	**Name, address of Applicant/Importer**	**M/s Bristol Mayer Biotech Pakistan** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt
	Details of Drug Sale License of importer	**License No:** 05-352-0068-109282D **Address:** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt **Address of Godown:** NA **Validity:** 18.10.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Sanzyme (P) Limited** Plot No. 8,Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name, address of manufacturer (s)	**Sanzyme (P) Limited** Plot No. 8,Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name of exporting country	India

	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copyof CoPP (No. 4116240/TS/2023) issued by Drugs Control Administration Government of Telangana for **Endogen HP 150 IU** valid upto 08/03/2026. The CoPP states that the product is **on free sale in exporting country**. **Free Sale Certificate:** Firm has submitted original, legalized copy of Free Sale Certificate (L. Dis. No: 116385/TS/2023) dated 25/04/2023 issued by Drugs Control Administration Government of Telangana for **Endogen HP 150 IU** valid up to 23/04/2024. The Free Sale Certificate states that the product is **on free sale in exporting country.** **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (L. Dis No: 100098/TS/2023) dated 10/03/2023 issued by Drugs Control Administration Government of Telangana valid upto 08/02/2026.
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **Sanzyme (P) Ltd.** The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to register their products in Pakistan. The authorization letter is valid till 08h February, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No: 8817 Date of submission: 31-03-2023
	Details of fee submitted	Rs: 150,000 Slip number: 95868629717 Dated : 09-03-2023
	The proposed proprietary name/ brand name	**Endogen HP 150 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Highly Purified Urofollitropin for Injection (Follicle Stimulating Hormone) 150 IU
	Pharmaceutical form of applied drug	Lyophilized powder for Injection (vial) packed along with 1 ml ampoule Sodium Chloride 0.9% w/v
	Pharmacotherapeutic Group of (API)	Gonadotrophins ATC code: G03G A04
	Reference to Finished product specifications	BP

	Proposed Pack size	1's (vial & ampoule)
	Proposed unit price	Rs. 3500/1's
	Shelf Life	3 years
	Storage Conditions	2°C to 8°C. It should not be allowed to freeze.
	The status in reference regulatory authorities	Swissmedic (Switzerland) Approved Fostimon 150 IU by IBSA InstitutBiochimique SA
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Shanghai Techwell Biopharmaceutical Co., Ltd. Address: No. 4258, Jindu Road, Shanghai 201108, China Tel: +86-21-54427100 Fax: +86-21-54426560 Email: liyan@techwell-cn.com Website: http://www.techwell-cn.com
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability data is conducted at 2-8 °C for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product
	Container closure system of the drug product	**Glass Vial:** 2 ml USP Type I Clear glass vial with 13 mm mouth outer diameter **Rubber stoppers :**13mm slotted grey bromobutyl rubber stopper(Type-I),(RFU) **Flip off seals:**13mm Aluminium flip off seal **Accompanying Diluent :**2ml USP Type-I, Clear glass ampoules(OPC) for diluent
	Stability study data of drug product, shelf life and	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at Temperature at 25°C

	storage conditions	± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted Temperature 5± 3°C for 36 months as per ICH guidelines.
	Module-IV Non-Clinical	Toxicology studies were performed. Single-dose toxicity4.2.3.1 and Repeat-dose toxicity4.2.3.2 data was presented.
	Module-V Clinical	5.3.5.1 Study Reports of Controlled clinical Studies Pertinent to the claimed Indication were presented on 174 subjects. Clinical Study Report (5.3.5.1) with title **"**A Prospective, Randomized, Open-label, Concurrent-controlled, three arm Study to Compare the Clinical Efficacy and Tolerability of Different Follicle-stimulating Hormone (Endogen® HP, Sanzyme vs Fostimon®, IBSA) and Human Chorionic Gonadotropin (Pubergen® HP, Sanzyme vs Pregnyl®, MSD Ltd) Combinations in Women Undergoing In Vitro Fertilization". The data from this study showed that we can conclude that Endogen is comparable to Fostimon; and Pubergen is comparable to Pregnyl in terms of primary and secondary efficacy endpoints, and that no statistical significant difference was observed between the 3 treatment groups, thus indicating the non-inferiority of test products as compared to the reference products. Under 5.3.6 Reports of post marketing experience, Periodic safety update report is also presented from 01st January 2021 to 31st December 2021.
	Remarks of Evaluator	
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

Molecule: Human Chorionic Gonadotropin (HCG)
Evaluator: Ms. Haleema Shareef

16.	**Name, address of Applicant/ Importer**	**M/s Bristol Mayer Biotech Pakistan** 73-B, Guldasht Town, ZarrarShaheed Road, Lahore Cantt
	Details of Drug Sale License of importer	**License No:** 05-352-0068-109282D **Address:** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt **Address of Godown:** NA **Validity:** 18.10.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Sanzyme (P) Limited** Plot No.8, Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name, address of manufacturer (s)	**Sanzyme (P) Limited** Plot No.8, Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copyof CoPP (No. 4116225/TS/2023) issued by Drugs Control Administration Government of Telangana for **Pubergen HP 1000 IU** valid upto 08/03/2026. The CoPP states that the product is **on free sale in exporting country**. **Free Sale Certificate:** Firm has submitted original, legalized copy of Free Sale Certificate (L. Dis. No: 116384/TS/2023) dated

		25/04/2023 issued by Drugs Control Administration Government of Telangana for **Pubergen HP 1000 IU** valid upto 23/04/2024. The Free Sale Certificate states that the product is **on free sale in exporting country** **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (L. Dis No: 10098/TS/2023) dated 10/03/2023 issued by Drugs Control Administration Government of Telangana valid up to 08/03/2026.
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **Sanzyme (P) Ltd.** The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to register their products in Pakistan. The authorization letter is valid till 08h February, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No: 8816 Date of submission: 31-03-2023
	Details of fee submitted	Rs: 150,000 Slip number: 9627286929 Dated : 09-03-2023
	The proposed proprietary name/ brand name	**Pubergen HP 1000 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Highly Purified Human Chorionic Gonadotropin for Injection1000 IU
	Pharmaceutical form of applied drug	Lyophilized powder for Injection (vial) packed along with 1 mL ampoule Sodium Chloride 0.9% W/v
	Pharmacotherapeutic Group of (API)	Gonadotrophins ATC code: G03G A04
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (vial & ampoule)
	Proposed unit price	Rs. 3500/1's
	Shelf Life	3 years
	Storage Conditions	2°C to 8°C. It should not be allowed to freeze.
	The status in reference regulatory authorities	Italian Medicine Agency (AIFA), ItalyApproved PREGNYL1000 IU by N.V. ORGANON
	For generic drugs (me-too status)	**Reg. No:**070930 **Company Name:** RG Pharmaceutica (Pvt) Ltd., Karachi **Brand Name:** Ferti ® C **Formulation:** Human Chorionic Gonadotrophin for Injection...1000 IU

		Pack Size:1's (vial & ampoule)
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Shanghai Techwell Biopharmaceutical Co., Ltd. Address: No. 4258, Jindu Road, Shanghai 201108, China Tel: +86-21-54427100 Fax: +86-21-54426560 Email: liyan@techwell-cn.com Website: http://www.techwell-cn.com
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability data is conducted at 2-8 °C for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product
	Container closure system of the drug product	**Glass Vial:** 2 ml USP Type I Clear glass vial with 13 mm mouth outer diameter **Rubber stoppers :**13mm slotted grey bromobutyl rubber stopper(Type-I),(RFU) **Flip off seals:**13mm Aluminium flip off seal **Accompanying Diluent :**2ml USP Type-I, Clear glass ampoules(OPC) for diluent
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at Temperature at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted Temperature 5± 3°C for 36 months as per ICH guidelines.
	Module-IV Non-Clinical	Toxicology studies were performed. Single-dose toxicity4.2.3.1 and Repeat-dose toxicity4.2.3.2 data was presented.
	Module-V Clinical	5.3.5.1 Study Reports of Controlled clinical Studies Pertinent to the claimed Indication were presented on 165 subjects.

		Clinical Study Report (5.3.5.1) with title **"**A Prospective, Randomized, Open-Label, Controlled, Clinical Study to Compare the Clinical Efficacy and Tolerability of Two Highly Purified Human Menopausal Gonadotropin Preparations Administered Subcutaneously in Women Undergoing In Vitro Fertilization". The data from this study showed that we can conclude that Endogen is comparable to Fostimon; and Pubergen is comparable to Pregnyl in terms of primary and secondary efficacy endpoints, and that no statistical significant difference was observed between the 3 treatment groups, thus indicating the non-inferiority of test products as compared to the reference products.
	Remarks of Evaluator	
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
17.	**Name, address of Applicant/Importer**	**M/s Bristol Mayer Biotech Pakistan** 73-B, Guldasht Town, ZarrarShaheed Road, Lahore Cantt
	Details of Drug Sale License of importer	**License No:** 05-352-0068-109282D **Address:** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt **Address of Godown:** NA **Validity:** 18.10.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Sanzyme (P) Limited** Plot No. 8,Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name, address of manufacturer (s)	**Sanzyme (P) Limited** Plot No. 8,Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copyof CoPP (No. 4116230/TS/2023) issued by Drugs Control Administration Government of Telangana for **Pubergen HP 2000 IU** valid upto 08/03/2026. The CoPP states that the product is **on free sale in exporting country**. **Free Sale Certificate:** Firm has submitted original, legalized copyof Free Sale Certificate (L. Dis. No: 116384/TS/2023) dated 25/04/2023 issued by Drugs Control Administration Government of Telangana for **Pubergen HP 1500 IU** valid upto 23/04/2024. The Free Sale Certificate states that the product is **on free sale in exporting country** **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (L. Dis No: 10098/TS/2023) dated 10/03/2023 issued by Drugs Control Administration Government of Telangana valid upto 08/03/2026.

	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **Sanzyme (P) Ltd.** The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to register their products in Pakistan. The authorization letter is valid till 08h February, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No: 8815 Date of submission: 31-03-2023
	Details of fee submitted	Rs: 150,000 Slip number: 0981339093 Dated : 09-03-2023
	The proposed proprietary name/ brand name	**Pubergen HP 2000 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Highly Purified Human Chorionic Gonadotropin for Injection 2000 IU
	Pharmaceutical form of applied drug	Lyophilized powder for Injection (vial) packed along with 1 mL ampoule Sodium Chloride 0.9% w/v
	Pharmacotherapeutic Group of (API)	Gonadotrophins ATC code: G03G A04
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (vial & ampoule)
	Proposed unit price	Rs. 3500/1's
	Shelf Life	3 years
	Storage Conditions	2°C to 8°C. It should not beallowed to freeze.
	The status in reference regulatory authorities	Italian Medicine Agency (AIFA), Italy Approved PREGNYL 2000 IU by N.V. ORGANON
	For generic drugs (me-too status)	**Reg. No:**062294 **Company Name:** Universal Enterprises, Karachi **Brand Name: Manotropin 2000IU Injection** **Formulation:** Each vial contains:- Chorionic Gonadotrophin……2000iu **Pack Size:**1's (vial & ampoule)
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Shanghai Techwell Biopharmaceutical Co., Ltd. Address: No. 4258, Jindu Road, Shanghai 201108, China Tel: +86-21-54427100 Fax: +86-21-54426560 Email: liyan@techwell-cn.com Website: http://www.techwell-cn.com
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability data is conducted at 2-8 °C for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product
	Container closure system of the drug product	**Glass Vial:** 2 ml USP Type I Clear glass vial with 13 mm mouth outer diameter **Rubber stoppers :**13mm slotted grey bromobutyl rubber stopper(Type-I),(RFU) **Flip off seals:**13mm Aluminium flip off seal **Accompanying Diluent :**2ml USP Type-I, Clear glass ampoules(OPC) for diluent
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at Temperature at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted Temperature 5± 3°C for 36 months as per ICH guidelines.
	Module-IV Non-Clinical	Toxicology studies were performed. Single-dose toxicity4.2.3.1 and Repeat-dose toxicity4.2.3.2 data was presented.
	Module-V Clinical	5.3.5.1 Study Reports of Controlled clinical Studies Pertinent to the claimed Indication were presented on 174 subjects. Clinical Study Report (5.3.5.1)with title **"**A Prospective, Randomized, Open-label, Concurrent-controlled, Three arm Study to Compare the Clinical Efficacy and Tolerability of Different Follicle-stimulating Hormone (Endogen® HP, Sanzyme vs Fostimon®, IBSA) and Human

		Chorionic Gonadotropin (Pubergen® HP, Sanzyme vs Pregnyl®, MSD Ltd) Combinations in Women Undergoing In Vitro Fertilization". **Conclusion:** we can conclude that Endogen is comparable to Fostimon; and Pubergen is comparable to Pregnyl in terms of primary and secondary efficacy endpoints, and that no statistical significant difference was observed between the3 treatment groups, thus indicating the non-inferiority of test products as compared to the reference products.
	Remarks of Evaluator	
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

Evaluator: Mr. Muhammad Kashif

18.	Name, address of Applicant / Importer	M/s ORGANS PHARMA Address: Block A, 6th Floor, Plot No. FD 35-36-A7, National Industrial Park, Korangi Creek Karachi.
	Details of Drug Sale License of importer	M/s ORGANS PHARMA Address: Block A, 6th Floor, Plot No. FD 35-36-A7, National Industrial Park, Korangi Creek Karachi. License No.: 0616 Valid till: 26.09.2028
	Name and address of marketing authorization holder (abroad)	M/s EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY (EIPICO) Manufacturing site: 10th of Ramadan city-first Industrial Area B1-P.O Box: 149 Tenth –Egypt
	Name, address of manufacturer(s)	M/s EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES COMPANY (EIPICO) Manufacturing site: 10th of Ramadan city-first Industrial Area B1-P.O Box: 149 Tenth –Egypt
	Name of exporting country	Arab Republic of Egypt
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (01686/2022/H) issued by the Arab Republic of Egypt EGYPTIAN DRUG AUTHORITY Central Administration for pharmaceutical products dated 10th October, 2022. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every two years.
		DML/DATA CERTIFICATE: Firm has submitted Original legalized (Code No. FM-LPF-02, Serial: 00013 /2019) Data Certificate of Pharmaceutical Plant Egyptian International Pharmaceutical Industries Company (EIPICO) for Human with activity code no. (2100), Operation licenses No. (112019031800003) issued by Ministry of Health & Population Central Administration for Pharmaceutical Affairs General Directorate of Pharmaceutical Licensing, Department of Licensing Pharmaceutical Products Factories. The certificate is issued on November 01,2018.

		GMP: Firm has submitted Original legalized GMP for Factory 1: First Industrial Area B1 (Certificate No: 1013/2021) Factory 2: Block Number Extension of B1-Industries Zone B1(Certificate No: P-900/2022) 10th of Ramadan city-Sharkia, Egypt, P. O. Box 149-10th. issued by Arab Republic of Egypt EGYPTIAN DRUG AUTHORITY Central Administration of Operations. The certificate is valid until 27/10/2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted Original Legalized Letter of authorization from Chairman and managing director Dr. Ahmed Kelani of EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. A.R.E authorizes "ORGANS PHARMA, with its place of business at: Block A, 6th Floor, Plot No. FD 35-36-A7, National Industrial Park, Korangi Creek Karachi. as their business representative with undisputed powers authorized to deal with the product registration of EPIFASI (Human Chorionic Gonadotropin) 5000 I.U Ampoules (Lyophilized Powder for IM Injections) in Pakistan as per mutually agreed terms and conditions by both companies. The letter was issued on January 16th, 2024 and valid for one year from its date.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No.6349 dated 06-March-2023
	Details of fee submitted	(Rs. 150,030/-) Slip No. 292379019172 dated 08-12-2022
	The proposed proprietary name / brand name	**EPIFASI 5000 IU** (Lyophilized Powder for IM Injections)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	EPIFASI 5000 I.U lyophilized ampoules consist of a freeze-dried powder for injection Human Chorionic Gonadotrophin 5000 I.U in 3mL Ampoule with 1 mL ampoule of solvent (sodium chloride 9 mg/mL)
	Pharmaceutical form of applied drug	Each 3mL ampoule of EPIFASI (HCG) 5000 IU Injection is a white to almost white lyophilized freeze-dried powder without any visible impurities. Filled in colorless, transparent glass with excipients: 1- Mannitol….10mg 2- Dipotassium hydrogen phosphate …0.464mg 3- Potassium dihydrogen phosphate …0.363mg 4- 0.15M acetic acid or 0.1N Sodium hydroxide…..qs to pH 6.5 5- water for Injection

		With 1mL ampoule of solvent Sodium Chloride (9 mg/mL) is a clear sterile colorless Solution preserved in single dose colorless glass ampoule. It is produced for parenteral use either for intravenous or intramuscular injection for reconstitution.
	Pharmacotherapeutic Group of (API)	Human Chorionic Gonadotrophin is sex hormones and modulators of the genital system. ***Code ATC:*** G03G A01. CAS Registry Number: 9002-61-3
	Reference to Finished product specifications	The specification of Chorionic Gonadotropin manufactured is established according to USP
	Proposed Pack size	1's, Carton Box contains EPIFASI 5000 I.U lyophilized freeze-dried powder for injection Human Chorionic Gonadotrophin 5000 I.U in 3mL Ampoule with 1 mL ampoule of solvent (sodium chloride 9 mg/mL)
	Proposed unit price	As per latest SRO & Retrospective CPIs
	Shelf Life	24 months
	Storage Condition	Store below 30°C
	The status in reference regulatory authorities	Pregnyl 5000 IU from MSD Company-Baxter Pharmaceutical Solutions for Organon, USA (Authorized in EEA)
	For generic drugs (me-too status)	IVF-C 5000 IU Injection (Galaxy Pharma (Pvt) Ltd., Karachi) Reg. No.: 039811
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Qingdao Kangyuan Pharmaceutical Co., Ltd. Address: Yinghai Industrial Park, Jiaozhou City, Qingdao, Shandong, China ,266300 Manufacturing Site 1: Name: Qingdao Kangyuan Pharmaceutical Co., Ltd. Address: Yinghai Industrial Park, Jiaozhou City, Qingdao, Shandong, China,2663009 (HCG Manufacturing, testing and releasing) Manufacturing Site 2: Name: Shandong Hailong Biotechnology Co., Lt. Address: North of Huaihai Road in Economic and Technological Development Zone, Junan, Shandong Province (Manufacturing of HCG Adsorbate) Manufacturing Site 3: Name: Yishui Longteng Biotechnology Co., Ltd. Address: D Road of North Program Zone, Yishui Xian Economic Development Zone (Manufacturing of HCG Adsorbate)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system

		and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of HCG at accelerated and long-term conditions. The long-term stability data is conducted at 5±3°C for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted Assay Method Validation by performing linearity, accuracy, precision, and robustness.
	Container closure system of the drug product	EPIFASI 5000 I.U Lyophilized powder for Injection is packed in 3.0 ml white transparent ampoule glass containers type I Solvent Ampoule: Sodium Chloride Injection BP 0.9% Ampoules are packed into Ph Eur 1 ml type I glass Ampoule.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. **For EPIFASI 5000IU Ampoule:** Three batches of EPIFASI 5000 I.U B-1510793, B-1602090 & B-1608742 were tested in stability study under both accelerated conditions at 40ºC/ 75% RH and ambient condition at 30ºC/ 65% RH. (Stable for 24 months). Batch no. B-1510793, B-1602090, B-1608742 **For Solvent Ampoule:** Three batches of 0.9% Sodium Chloride Ampoules were tested in stability study under accelerated conditions at 40ºC/ 75% RH and ambient condition at 30ºC/ 65% RH. (Stable for 48 months) Batch no. 150154, 160030, 160263
	Module IV	The firm has submitted statement that Module IV is not applicable as according to ICH Guidelines, non-clinical study is performed by innovator only, and as Epifasi 5000 IU Lyophilized Powder for Injection is generic product, the non-clinical study is not required, so module 4 not applicable in this product. Firm has y submitted the statement The Marketing Authorization Application for the drug product EPIFASI 5000 I.U Lyophilized powder for solution for injection is provided with bio similarity study report but according to the provisions in Article 10.1 (a) of Directive 2001/83/EC (The applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognized efficacy and an acceptable level of safety in terms of the conditions set out in the Annex. In that event, the test and trial results shall be replaced by appropriate scientific literature.) EPIFASI 5000 I.U is claimed to be essentially similar to **Pregnyl® for Injection**, which has been authorised in the EEA for more than 15 years. MSD USA was granted authorisations for Pregnyl ® for Injection.

		The active constituent Human Chorionic Gonadotrophin is well recognized with an approved efficacy and an acceptable level of safety for more than 20 years.
	Module V	Comparative randomized, single dose, parallel, triple-blinded study in infertile females is performed to evaluate biosimilarity of IM Injection of Human Chorionic Gonadotrophin (HCG) after Parentral administration of Treatment A Test Product Epifasi 5000 I.U. Ampoules (EIPICO PHARMA, EGYPT) and Treatment B REFERENCE Product Pregnyl 5000 I.U. Ampoules (Baxter Pharmaceutical Solutions for Organon, USA).
	The firm has submitted Biosimilarity data as per following details:	

WHO Biosimilarity Guidelines	**Data Submitted by M/s Organs Pharma, Karachi**
Quality Comparison **4.** Physicochemical Characterization	

Category	**Quality Attributes**	**Analytical methods**
Physicochemical properties	Content and its weight	Visual, Balance
	Rate of solution	Shaking
	PH 1% (W/V)	PH meter
	Moisture Content	Coulometer
	Uniformity of dosage unites By Weight variation	Balance
	Clarity and color of solution	Visual
	Identification for Chorionic gonadotrophin	Biologically
	Assay for HCG	Pharmacology and toxicology
Microbiological test	Sterility	Sterility test apparatus
	Bacterial Endotoxin	LAL test
	Safety test and Particulate matter Sub visible	Microanalysis

Stability Studies	The firm has submitted stability studies.

Non-clinical Comparison I. *In-vitro* Studies II. *In-vivo* Studies a) Biological / Pharmacodynamic activity b) Non- clinical Studies	***Pharmacodynamics:*** Epifasi (Human Chorionic Gonadotrophin; HCG) is a polypeptide hormone produced by the placenta and obtained from the urine of pregnant women. Its effects are mainly those of the gonadotrophin, luteinizing hormone (which is secreted from the pituitary gland), and is responsible for triggering ovulation and formation of the corpus luteum which leads to the production of progesterone in women. HCG has a small degree of follicle stimulating hormone (FSH) activity. In normal pregnancy, HCG secreted by the placenta maintains the corpus luteum after LH secretion decreases, supporting continued secretion of estrogen and progesterone, and preventing menstruation. In men: It stimulates and maintains spermatogenesis in men with hypogonadotropic hypogonadism. ***Pharmacokinetics:*** Following intramuscular administration, peak plasma concentrations are achieved within about 6 hours after a dose. It is distributed primarily to the gonads. Blood concentrations decline in a biphasic manner, with half-lives of about 6 – 11 hours and 23 – 38 hours respectively. Chorionic gonadotrophin is metabolized mainly in the kidneys. About 10 –12% of a dose is excreted in urine within 24 hours. ***Toxicity:*** Taking high, a dose of EPIFASI may cause hyper stimulation of the ovaries. This may be noticed as pain in the abdomen. These depend on dosage, duration of therapy, and individual susceptibility. Possible side effects include headache, irritability, tiredness, restlessness, edema (especially in males), acute abdominal pain, ascites, pleural effusion, hypovolemia, premature epiphyseal closure or precocious puberty, gynecomastia, pain at injection site, aggressive behavior, ovarian hyperstimulation syndrome, enlargement of preexisting ovarian cyst and possible rupture, arterial thromboembolism, and multiple births. Hypersensivity reactions both localized and systemic in nature including erythema, urticaria, rash, angiodema, dyspnea has been reported. Firm has also submitted the statement that According to ICH Guidelines, non-clinical study is performed by innovator only, and as Epifasi 5000 IU Lyophilized Powder for Injection is generic product. The Marketing Authorization Application for the drug product EPIFASI 5000 I.U Lyophilized powder for solution for injection is provided with bio similarity study report but according to the provisions in Article 10.1 (a) of Directive 2001/83/EC (The applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognized efficacy and an acceptable level of safety in terms of the conditions set out in the Annex. In that event, the test and trial results shall be replaced by appropriate scientific literature.) EPIFASI 5000 I.U is claimed to be essentially similar to Pregnyl® for Injection, which has been authorised in the EEA for more than 15 years. MSD USA was granted authorisations for Pregnyl ® for Injection. The active constituent Human Chorionic Gonadotrophin is well recognized with an approved efficacy and an acceptable level of safety for more than 20 years.

Clinical Studies	Firm has already submitted the clinical study which was performed to investigate the bio similarity of Human Chorionic Gonadotrophin (HCG) from Epifasi 5000 I.U. Ampoules (EIPICO Pharma, Egypt) and Pregnyl 5000 I.U. Ampoules (Baxter Pharmaceutical Solutions for Organon, USA). The study protocol called for 60female volunteers. The Patients received a single dose of 2 Amps. (10000) of Human chorionic gonadotropin by deep IMI at 10 pm to induce final follicular maturation prior to ovum pick-up (OPU) after 35-36 hours according to randomization scheme. All parameters were calculated using SPSS statistical software. Chi-Square (Fisher's Exact Test if Chi-Square is not applicable), p-values for the difference in proportions for all the categorical variables (i.e.: sex: male/female), Two sample T-tests (Wilcoxon-Mann-Whitney test if Student's T-Test is not applicable) will be performed for the continuous variables (i.e.: Age). The statistical analysis was performed using 60 subjects. In conclusion, the study demonstrated that the Treatment A TEST Product Epifasi 5000 I.U. Ampoules (EIPICO Pharma, Egypt) is bioequivalent to the Treatment B REFERENCE Product Pregnyl 5000 I.U. Ampoules (Baxter Pharmaceutical Solutions for Organon, USA). This report is issued in consensus with the ICH guidelines concerning the structure and content of the clinical study report adopted by EMEA7
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Molecule: Human Immunoglobulin
Evaluator: Ms. Haleema Shareef

19.	**Name, address of Applicant / Importer**	M/s. Immunowell (Pvt) ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Details of Drug Sale License of importer	**License No.**05-352-0066-100098D **Address**: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan **Validity:**17-Nov-2027 **Status**: License to sell, stock & exhibit for sale, distributor registered products on behalf of licensed pharmaceuticals manufacturer as his authorized agent on the premises
	Name and address of marketing authorization holder (abroad)	M/s. Immunowell (Pvt) Ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Name, address of manufacturer(s)	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economicand Technological Development Zone, Heilongjiang Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm has submitted original, Legalized CoPP (No. Heilongjiang 20220023) issued on 21-06-2022, valid upto 20-06-2024, issued by Heilongjiang Medical Products Administration, China. Legalized GMP Inspection Report issued by Heilongjiang Medical Products Administration, China.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific with brand name Globin Well I.V. inj letter of Authorization, from Harbin Pacific Biopharmaceutical Co., Ltd according to the letter, M/s. Harbin Pacific Biopharmaceutical Co., Ltd appoints Immunowell (Pvt)

		Ltd with address 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan It's representative for sole purpose of registration of the said product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. Dated: 02-Jan-2022
	Details of fee submitted	Rs.150, 000/- slip No.029922813 dated: 29-12-2022
	The proposed proprietary name / brand name	**Globin Well I.V. inj.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Immunoglobulin IgG….. 2.5gm.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Intravenous Immunoglobulin
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2.5gm/50mL Vial
	Proposed unit price	Rs. 38,398/Vial
	Shelf Life	36 months
	Storage Conditions	$2^{O}C$ - $8^{O}C$
	The status in reference regulatory authorities	Gamimune 5% (Immune Globulin Intravenous) Approved by USFDA.
	For generic drugs (me-too status)	I.V. Globulin SN Injection registered in Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubility, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification ,

		reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterization of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economicand Technological Development Zone, Heilongjiang Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Bulk solution of human immunoglobulin for intravenous injection is a transitional phase, so the stability studies are inapplicable.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical methods as per in House Specs. Validation of analytical procedures, process validation, batch analysis and stability studies have been performed.
	Container closure system of the drug product	Injection vial made of molecule middle borosilicate glass, halogenated butyl rubber stopper for injection (brominated) and aluminum-plastic combination cap.
	Stability study data of drug product, shelf life and storage conditions	The studies are performed according to the current ICH stability guidelines. The studies cover long term storage conditions (2°C - 8°C) for 36 months and accelerated storage conditions (25°C±2°C) 60%±5% RH for 6 months.

		Based on the results from the long term and accelerated stability studies, the proposed shelf life of 36 months at 2°C ± 8°C
	Module-IV	Not submitted
	Module-V	Not submitted
	Remarks	• Firm has not provided stability studies of drug substance with this justification that drug substance stability data is not required in china. • Firm has not provided safety and efficacy data with this justification that brands like Gamarrass, HL Globin and our product are being used in china from decades and their safety and efficacy is established for many decades. So Module IV and V are exempted.
Decision: Registration Board deferred the product for submission of: • **Stability studies data of drug substance/evidence of ICH guideline indicating no requirement of stability data for this substance.** • **Safety and efficacy studies of applied formulation/ evidence of ICH guideline indicating no requirement of safety and efficacy data for applied formulation.**		

Molecule: Pneumococcal 13-Valent
Evaluator: Ms. Haleema Shareef

20.	**Name, address of Applicant / Importer**	M/s. Immunowell (Pvt) ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Details of Drug Sale License of importer	**License No.**05-352-0066-100098D **Address**: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan **Validity:**17-Nov-2027 **Status**: License to sell, stock & exhibit for sale, distributor registered products on behalf of licensed pharmaceuticals manufacturer as his authorized agent on the premises
	Name and address of marketing authorization holder (abroad)	M/s. Immunowell (Pvt) ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Name, address of manufacturer(s)	M/s Beijing Minhai Biotechnology Co., Ltd., No. 35 Simiao Road and No. 25 Tianfu Street, Bioengineering&Pharmaceutical Industrial Park, Zhongguancun Science Park, Daxing District, Beijing CHINA
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm submitted Legalized, original CoPP with brand name. Firm has submitted revised original legalized CoPP with generic name No. Beijing20230099, issued on 04-04-2023 issued by Beijing Medical Products Administration, China. Legalized GMP Inspection Report issued by Beijing Medical Products Administration, China.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter with brand name PneumoLing-13 of Authorization from Beijing Minhai Biotechnology Co., Ltd., according to the letter, M/s. Beijing Minhai Biotechnology appoints Immunowell(Pvt) Ltd with

<table>
<tr><td></td><td></td><td>address 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan.
It’s representative for sole purpose of registration of the said product.</td></tr>
<tr><td></td><td>Status of the applicant</td><td>☐ Manufacturer
☒ Importer
☐ Is involved in none of the above (contract giver)</td></tr>
<tr><td></td><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td>☒ Domestic sale
☐ Export sale
☐ Domestic and Export sales</td></tr>
<tr><td></td><td>For imported products, specify one the these</td><td>☒ Finished Pharmaceutical product import
☐ Buk import and local repackaging
☐ Buk import and local repackaging for export purpose only</td></tr>
<tr><td></td><td>Dy. No. and date of submission</td><td>Dy. No. Dated: 30-March-2023</td></tr>
<tr><td></td><td>Details of fee submitted</td><td>Rs.150, 000/- via e-deposit slip No.003740473827 dated: 29-03-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>PneumoLing-13 pre-filled syringe The firm has submitted the NOC from manufacturer confirming the supply of Pneumococcal vaccine 13 vaccine with the brand name PneumoLing-13.</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>13-Valent Pneumococcal Polysaccharide Conjugated Vaccine (TT/DT) Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION
<table>
<tr><td>1 dose (0.5 ml) contains: Pneumococcal polysaccharides serotype 1 ….1.8 ug</td><td>Pneumococcal polysaccharides serotype 9V ….2.3 ug</td></tr>
<tr><td>Pneumococcal polysaccharides serotype 3 …..2.1 ug</td><td>Pneumococcal polysaccharides serotype 14 ….1.35 ug</td></tr>
<tr><td>Pneumococcal polysaccharides serotype 4 ….2.1 ug</td><td>Pneumococcal polysaccharides serotype 18C ….3.65 ug</td></tr>
<tr><td>Pneumococcal polysaccharides serotype 5 ….1.75 ug</td><td>Pneumococcal polysaccharides serotype 19A ….1.6 ug</td></tr>
<tr><td>Pneumococcal polysaccharides serotype 6A ….1.85 ug</td><td>Pneumococcal polysaccharides serotype 19F ….1.25 ug</td></tr>
<tr><td>Pneumococcal polysaccharides serotype 6B ….4.4 ug</td><td>Pneumococcal polysaccharides serotype 23F ….2.35 ug</td></tr>
<tr><td colspan="2">Pneumococcal polysaccharides serotype 7F…. 1.75 ug</td></tr>
</table></td></tr>
<tr><td></td><td>Dosage form of applied drug</td><td>Prefilled Syringe</td></tr>
</table>

	Pharmacotherapeutic Group of (API)	Conjugated Vaccine
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	0.5ml/dose/pack prefilled syringe
	Proposed unit price	Rs.7,084.61/dose/pack
	Shelf Life	24 months
	Storage Conditions	$2^{O}C$ - $8^{O}C$
	The status in reference regulatory authorities	PREVENAR 13 is approved in USFDA
	For generic drugs (me-too status)	PREVENAR 13 registered in Pakistan, USA and many other countries in the world.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubilities, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterisation of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Beijing Minhai Biotechnology Co., Ltd., No. 35 Simiao Road and No. 25 Tianfu Street, Bioengineering & Pharmaceutical Industrial Park, Zhongguancun Science Park, Daxing District, Beijing CHINA
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The studies cover long term storage conditions (5°C ± 3°C) for 24 months. Accelerated stability test performed at 25±2°C for 28 days.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical methods as per In House Specs. The methods are Validated as per SOP's. The Analytical methods are as follows: Method suitability test for sterility test of aluminum phosphate Adjuvant. Method verification test for bacterial endotoxin in aluminum phosphate adjuvant. pH Sodium chloride content Osmolarity Phenol content Content of polysaccharide Sterility test Abnormal toxicity test Bacterial endotoxins test Pyrogen test
	Container closure system of the drug product	The primary packaging of PCV13 is an assemblage for prefilled syringe (with stainless steel needle), which includes accessories of a glass barrel for prefilled syringe (with stainless steel needle), plunger rod, plunger, needle and needle shield. Among them, the barrel, plunger and needle are in direct contact with the drug liquid.
	Stability study data of drug product, shelf life and storage conditions	The studies cover long term storage conditions (5°C ± 3°C) for 36 months and accelerated storage conditions (25°C±2°C) for 6 months. Based on the results from the long term and accelerated stability studies, the proposed shelf life of 36 months at 5°C ± 3°C
	Module-IV	The Firm has submitted following non-clinical studies: **1.** Single Dose Toxicity Test of 13-valent Pneumococcal Conjugate Vaccine in Rats. **2.** Muscle Irritation Test of 13-valent Pneumococcal Conjugate Vaccine in Rabbits. **3.** Active Systemic Anaphylaxis of 13-valent Pneumococcal Conjugate Vaccine in Guinea Pigs.

		4. Repeated Dose Toxicity Test and Accompanying Immunogenicity Rest of 13-valent Pneumococcal Conjugate Vaccine in Rats
	Module-V	The Firm has submitted following clinical studies: **1.** A phase 3 clinical trial of MINHAI PCV13 in Chinese children aged from 7 months to 5 years old. **2.** Final Report of Clinical Trial of Minhai 13-Valent Pneumococcal Conjugate Vaccine. **3.** Immunogenicity and safety of a 13-valent pneumococcal conjugate vaccine administered in a prime-boost regimen among Chinese infants: a randomized, double blind phase III clinical trial
	Remarks	
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

Molecule: Pneumococcal 23-Valent
Evaluator: Ms. Haleema Shareef

21.	**Name, address of Applicant / Importer**	M/s. Immunowell (Pvt) ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Details of Drug Sale License of importer	**License No.**05-352-0066-100098D **Address**: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan **Validity:**17-Nov-2027 **Status**: License to sell, stock & exhibit for sale, distributor registered products on behalf of licensed pharmaceuticals manufacturer as his authorized agent on the premises
	Name and address of marketing authorization holder (abroad)	M/s. Immunowell (Pvt) ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Name, address of manufacturer(s)	M/s Beijing Minhai Biotechnology Co., Ltd., No. 35 Simiao Road and No. 25 Tianfu Street, Bioengineering&Pharmaceutical Industrial Park, Zhongguancun Science Park, Daxing District, Beijing CHINA
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm submitted original, Legalized CoPP with brand name. Firm has submitted revised original Legalized CoPP with generic name (No. Beijing20220118) issued on04-04-2023, valid upto 11-08-2023, issued by Beijing Medical Products Administration, China. Original, Legalized GMP Certificate No. 231100B0/01159, dated: 27-Feb-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter with brand name PneumoLing-23 of Authorization from Beijing Minhai Biotechnology Co., Ltd., according to the letter, M/s. Beijing Minhai Biotechnology appoints Immunowell(Pvt) Ltd with address 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan. It's representative for sole purpose of registration of the said product.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. Dated: 30-March-2023
	Details of fee submitted	Rs.150, 000/- slip No.978799148944 dated: 29-03-2023
	The proposed proprietary name / brand name	**PneumoLing-23 pre-filled syringe.** The firm has submitted the NOC from manufacturer confirming the supply of Pneumococcal vaccine 23 vaccine with the brand name PneumoLing-23.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	The 0.5 mL dose of vaccine contains 25 µg of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	23-Valent Pneumococcal Polysaccharide Vaccine, Solution for injection in pre-filled syringe
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	0.5ml/dose/pack prefilled syringe
	Proposed unit price	Rs.6,300/dose/pack
	Shelf Life	24 months
	Storage Conditions	$2^{O}C$ - $8^{O}C$
	The status in reference regulatory authorities	Pneumovax of MSD approved in USFDA
	For generic drugs (me-too status)	Pnumo 23 registered in Pakistan and Pneumovax of MSD is registered USA, Europe and many other countries in the world.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubilities, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other

		characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterisation of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Beijing Minhai Biotechnology Co., Ltd., No. 35 Simiao Road and No. 25 Tianfu Street, Bioengineering&Pharmaceutical Industrial Park, Zhongguancun Science Park, Daxing District, Beijing CHINA
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The studies cover long term storage conditions (-30°C) for 42 months. Accelerated stability conducted at -5°C±3°C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical methods as per In House Specs. The methods are Validated as per SOP's. The Analytical methods are as follows: pH Sodium chloride content Osmolarity Phenol content

		Content of polysaccharide Sterility test Abnormal toxicity test Bacterial endotoxins test Pyrogen test
	Container closure system of the drug product	The primary packaging of PPSV23 is an assemblage for prefilled syringe (with stainless steel needle), which includes accessories of a glass barrel for prefilled syringe (with stainless steel needle), plunger rod, plunger, needle and needle shield. Among them, the barrel, plunger and needle are in direct contact with the drug liquid.
	Stability study data of drug product, shelf life and storage conditions	The studies cover long term storage conditions (5°C ± 3°C) for 24 months. Accelerated stability test performed at 25±2°C for 28 days. Based on the results from the long term and accelerated stability studies, the proposed shelf life of 24 months at 5°C ± 3°C.
	Module-IV	The Firm has submitted following non-clinical studies: 1. Single Dose Toxicity Test of Intraperitoneal-Injected 23-Valent Pneumococcal Polysaccharide Vaccine in SPF BALB/CMice and CL Guinea Pigs. 2. Active Systemic Anaphylaxis Test of 23-Valent Pneumococcal Polysaccharide Vaccine in Guinea Pigs. 3. Immunogenicity Study of 13-Valent Pneumococcal Conjugate Vaccine (Auxiliary application for PPSV-23)
	Module-V	Firm has provided Final report of the single-center, randomized, double-blind, and parallel-controlled trial of 23-valent pneumococcal polysaccharide vaccine in healthy people A total of 1,200 subjects were enrolled in Phase III, including 600 in the test group and 600 in the control group.
	Remarks	
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

Imported human biological product *from Non-reference countries:*

Molecule: Infliximab

Evaluator: Ms. Anam Saeed

22.	Name, address of Applicant / Importer	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan. Tel: 021- 32591000 Ext.2007 FAX: 2564263, 2565854 & 2566894
	Details of Drug Sale License of importer	License No: 037 Address: F-216 SITE KARACHI Validity: 07-08-2023 Status: License to sell drugs by way of Whole sale.
	Name and address of marketing authorization holder (abroad)	M/s Taizhou Mabtech Pharmaceuticals Co., Ltd G79 Building, East of Lujia Road and West of Koutai Road, Chinese Medicine Center, Taizhou, Jiangsu, China

	Name, address of manufacturer(s)	M/s Taizhou Mabtech Pharmaceuticals Co., Ltd G79 Building, East of Lujia Road and West of Koutai Road, Chinese Medicine Center, Taizhou, Jiangsu, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (Certificate No.Jiangsu20230270) dated 2023-07-24 by People's Republic of China, Jiangsu Medical Products Administration (JSMPA). The certificate confirms that the product is actually on the market in the exporting country and facilities and operations conform to GMP as recommended by WHO. The certificate is valid till 23-07-2025.
	Details of letter of authorization / sole agency agreement	Legalized Licensing and Distribution Agreement is submitted by the firm.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	R&I(DRAP) Dy.No.20518 dated 20-July-2022
	Details of fee submitted	PKR 150000/- dated 20-05-2022 Deposit Slip No. 6908631185
	The proposed proprietary name / brand name	**FLIXIMAC**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Infliximab…….100mg
	Dosage form of applied drug	**Lyophilized powder for infusion**
	Pharmacotherapeutic Group of (API)	a) Act as IMMUNO SUPPRESSANT Tumor necrosis factor alpha (TNF-α) inhibitors (b) ATC code: L04AB02
	Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	1's Vial
	Proposed unit price	As per SRO
	Shelf Life	36 months

	Storage Conditions	Store at 2°C – 8°C
	Reference Regulatory Authorities	REMICADE 100 mg Powder for concentrate for solution for infusion" registered product of Janssen Biotech, Inc USA approved by FDA in August 1998 & approved by EMA in August 1999.
	For generic drugs (me-too status)	Remsima (088529) ATCO laboratories limited Pakistan Remicade (043098) Schering plough Pakistan (Pvt.) Ltd.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per template provided by DRAP. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Taizhou Mabtech Pharmaceuticals Co., Ltd. G79 Building, east of Lujia Road and west of Koutai Road, Chinese Medicine Center, Taizhou, Jiangsu, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted at (NMT-30°C) for 36 months on 3 batches. Accelerated is conducted at (2°C~8°C) for 6 months on 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and Stability.
	Analytical method Validation / verification of the product	The specifications & analytical procedures are submitted along with validation of Analytical Procedures.
	Container closure system of the drug product	The primary container closure system is medium borosilicate glass vial, chlorinated butyl rubber stopper (Covered with Teflon/vinyl copolymer) and aluminium plastic cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of FPP at accelerated and real time conditions. The real time stability data is conducted at (2-8°C) for 36 months on 3 batches. Accelerated is conducted at (25°C±2°C/60%±5%RH) for 6 months on 3 batches of FPP.
	Module-IV Non-Clinical	Firm has submitted following data: Pharmacodynamic study report of CMAB008 In vitro pharmacodynamic study report of CMAB008 for

		inflammatory bowel disease (IBD) In vivo pharmacodynamic study report of CMAB008 in a rat model of indomethacin-induced enteritis Study report on apoptosis induction of CMAB008 in hu-THP-1mouce chimeric model General pharmacological studies of CMAB008 Acute toxicity study data of CMAB008 Long-Term Toxicity Study Report of Recombinant Anti-TNFα Human-Mouse Chimeric Monoclonal Antibody (CMAB008) Intravenously Injected to Cynomolgus Monkeys for 30 Days Followed by a Recovery Period of 15 Vascular Irritation Study of CMAB008 CMAB008 Immunotoxicity Study Report Cross-Reactivity Between CMAB008 and Tissues and Organs of Cynomolgus Monkeys
	Module-V Clinical	Firm has submitted following data: Method validation report for quantitative determination of the concentration of CMAB008 or REMICADE® in human serum by ELISA (S2501MVHuSe01) Method validation report on qualitative assay of anti CMAB008 or anti-infliximab antidrug antibody in human serum by ace method based on eclia technique on MSD platform (S2501MVHuSe02) Method validation report of L-929 cell proliferation-based end point method to assay neutralizing antibody against the test article CMAB008 or the reference product infliximab in human serum (S2501MVHuSe03) Phase I single-dose PK and initial tolerability study report Healthy subject single-dose PK study report (compared to reference product) Phase I repeat-dose PK and tolerability study report Phase III PK analysis report of CMAB008 in patients with moderate to severe active rheumatoid arthritis (compared to reference product) Population PK study report of CMAB008 and reference product in medium to severe RA patient and healthy subject A Phase III, Randomized, Double-Blind, Multicenter Clinical Study with Remicade® as Reference and MTX as Basic Treatment to

		Evaluate the Efficacy and Safety of Recombinant Anti-Tumor Necrosis Factor-α Human-Mouse Chimeric Monoclonal Antibody (CMAB008) for Injection in the Treatment of Moderate to Severe Active Rheumatoid Arthritis in Adults.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

Molecule: Anthrax Vaccine (Vet)
Evaluator: Mr. Muhammad Kashif

Locally manufactured veterinary biological applied by M/s Hirra Pharmaceutical Laboratories Pvt Ltd., Lahore

23.	Name and address of manufacturer	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name +Dosage Form + Strength	**Hirra Anthra Vac Injection**
	Composition	Each mL contains: 10 millions of Avirulent Bacillus Anthracis Spore (Sterne strain) Vaccine
	Diary No. Date of R& I & fee	Dy. No.1286 dated 22-01-2023 Fee Rs. 30,000 (Deposit slip# 156851316)
	Pharmacological Group	Vaccine
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & Demanded Price	50mL; 100mL De-controlled
	Shelf life	18 months (2-8°C)
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Hirra Anthra Vac Injection by M/s Hirra Pharmaceuticals Reg#028549
	GMP status	New License DML # 000449 issued on 16-01-2024
	Remarks	Stability data, safety and efficacy studies are not required under Form-5, so the same are not provided by the applicant. Finished Product Specifications are not provided by the firm. **As per record of DRAP the "Hirra Anthra Vac Injection by M/s Hirra Pharmaceuticals Reg#028549" was locally registered.**
	Deliberation of 178th Authority Meeting:	Consideration of Application of Registrations Out of Queue: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. The request of M/s Hirra Pharmaceutical Laboratories, Lahore was

		presented in the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. The Authority in its 178th meeting, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for:- i. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and ii. Grant of same registration numbers and brand names.
Decision: Registration Board after detailed deliberations approved the product.		

Molecule: Pasteurella Vaccine (Vet)
Evaluator: Mr. Muhammad Kashif

24.	**Name and address of manufacturer**	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name +Dosage Form + Strength	Pasteurella Multocida Vaccine
	Composition	Each mL contains: Pasteurella Multocida ……. 0.75mL Mineral Oil…….. 1.57mL Formaldehyde…….. 0.05% per mL
	Diary No. Date of R& I & fee	Dy. No.1290 dated 22-01-2024 Fee Rs. 30,000 (Deposit slip# 452271821411)
	Pharmacological Group	Vaccine
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & Demanded Price	50mL 10 dose; 300mL 60 dose De-controlled
	Shelf life	18 months (2-8°C)
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Bio-HS Bacterin (oil based) injectable vaccine by M/s Bio-Labs Pvt Ltd, Islamabad (Reg# 017135)
	GMP status	New License DML # 000449 issued on 16-01-2024
	Remarks	Stability data, safety and efficacy studies are not required under Form-5, so the same are not provided by the applicant. Finished Product Specifications are not provided by the firm. As per record of PE&R division "Bio-HS Bacterin (oil based) injectable vaccine by M/s Bio-Labs Pvt Ltd, Islamabad (Reg# 017135)" is locally registered.
Deliberation of 178th Authority Meeting:	Consideration of Application of Registrations Out of Queue: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied	

	for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. The request of M/s Hirra Pharmaceutical Laboratories, Lahore was presented in the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. The Authority in its 178th meeting, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for:- i. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and ii. Grant of same registration numbers and brand names.
Decision: Registration Board after detailed deliberations approved the product.	

Molecule: R.C Medium (Vet)
Evaluator: Mr. Muhammad Kashif

25.	**Name and address of manufacturer**	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name +Dosage Form + Strength	**Hirra Entero Vaccine**
	Composition	Each 100mL contains: R.C. Medium…….. 3.7mg Formal Dehyde……0.37mg Potassium Aluminum Sulphate…0.2mg
	Diary No. Date of R& I & fee	Dy. No.1281 dated 22-01-2023 Fee Rs. 30,000 (Deposit slip# 32874512952)
	Pharmacological Group	Vaccine
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & Demanded Price	50mL 10 dose; 300mL 60 dose De-controlled
	Shelf life	18 months (2-8°C)
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	**Hirra Entero Vaccine** by M/s Hirra Pharmaceuticals Reg# 021414
	GMP status	New License DML # 000449 issued on 16-01-2024
	Remarks	Stability data, safety and efficacy studies are not required under Form-5, so the same are not provided by the applicant. Finished Product Specifications are not provided by the firm. As per record of PE&R division "Hirra Entero Vaccine by M/s Hirra Pharmaceuticals Reg# 021414" is locally registered.
	Deliberation of 178th Authority Meeting:	Consideration of Application of Registrations Out of Queue: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm. Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML

		number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. The request of M/s Hirra Pharmaceutical Laboratories, Lahore was presented in the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. The Authority in its 178th meeting, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for:- i. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and ii. Grant of same registration numbers and brand names.
Decision: Registration Board after detailed deliberations approved the product.		

Molecule: Saline-Formulated Liver Homogenate with antibiotics (Vet)
Evaluator: Mr. Muhammad Kashif

26.	**Name and address of manufacturer**	M/s. Hirra Pharmaceutical Laboratories Pvt Ltd., 1.3KM (Asil Raiwind Road, Ladhaky Bhular), Lahore, (DML No. 000449)
	Brand Name +Dosage Form + Strength	**Hydro Poultry Vaccine**
	Composition	Each dose contains: Homogenished Liver Formative Antibiotics (Streptomycin, Pronapen or Gentamycine) normal Saline
	Diary No. Date of R& I & fee	Dy. No.1283 dated 22-01-2023 Fee Rs. 30,000 (Deposit slip# 05863485353)
	Pharmacological Group	Vaccine
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & Demanded Price	125mL (500 doses); 250mL (100 doses); 500mL (2000 doses) De-controlled
	Shelf life	18 months (2-8°C)
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	**Hydro Poultry Vaccine** by M/s Hirra Pharmaceuticals Reg# 021415
	GMP status	New License DML # 000449 issued on 16-01-2024
	Remarks	Stability data, safety and efficacy studies are not required under Form-5, so the same are not provided by the applicant. Finished Product Specifications are not provided by the firm. As per record of PE&R division "Hydro Poultry Vaccine by M/s Hirra Pharmaceuticals Reg# 021415" is locally registered.
	Deliberation of 178th Authority Meeting:	Consideration of Application of Registrations Out of Queue: Drug Manufacturing License No.000449 by way of Formulation was issued to M/s Hirra Pharmaceutical Laboratories, Lahore. Application for renewal of DML for the period of 01-08-2020 to 31-07-2025 was not received within due time and CLB in its 279th meeting held on 18-02-2021 cancelled the License of the firm.

		Subsequently, the registrations were also cancelled due to cancellation of DML. The firm applied for re-grant of license and the CLB on the recommendations of panel of experts granted a fresh license to the firm in 295th meeting with the same DML number. After the issuance of DML, M/s Hirra Pharmaceutical Laboratories, Lahore applied for the restoration of its 20 registration certificates by submitting afresh applications on Form 5 being vet drugs alongwith full fee of registration. The request of M/s Hirra Pharmaceutical Laboratories, Lahore was presented in the Authority regarding the consideration of submitted applications of registration of out of Queue with same registration numbers and brand names. The Authority in its 178th meeting, keeping in view of the decision taken in the past, acceded to the request of M/s Hirra Pharmaceutical Laboratories, Lahore for:- i. Out-of-queue consideration of submitted applications of registrations of those drugs which were already registered with the firm before cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time and ii. Grant of same registration numbers and brand names.
Decision: Registration Board after detailed deliberations approved the product.		

Molecule: Paramyxovirus (Vet)
Evaluator: Ms. Haleema Shareef

27.	**Name and address of Importer**	**M/s. QAS International, Gujranwala**
	Detail of DSL	**M/s.QAS International,** Address: Opposite Marian Hotel Near Grace Marque Subhan Ceramics Main GT Road, Gujranwala Valid till: 24-Nov-2022.
	Name and address of Manufacturer	Manufacturer: M/s.PHARMAGAL BIO, s. r. o. Murgašova 5 949 01 Nitra Slovak Republic
	Name of exporting country	Slovak Republic
	Brand Name +Dosage Form + Strength	**COLUMBA** Emulsion for injection
	Diary No. Date of R& I & fee	Dy. No. 19148 R&I Dated 30-06-2022 Rs. 150,000/- (Slip No 80140391888)
	Composition:	One dose of the vaccine 0.3 ml contains: Inactivated pigeon paramyxovirus 1 strain 988M-ca inducing ≥ 5.8 $\log_2$ HI unit in chickens
	Pharmacological Group	Antiviral
	Finished Product Specification	In house
	Shelf Life	Shelf-life of the veterinary medicinal product as packaged for sale: 30 months
	Document Details	i. Firm has submitted original sole agency agreement valid for 5 years from date of signature i.e. 03.06.2022. ii. Original legalized CoPP (NO. 1166/I/2022) is submitted by the firm.
	Pack size & Price	50doses: Decontrolled

	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Could not be confirmed
	Remarks of Evaluator:	i. Product already registered in Pakistan could not be confirmed with tis strain type "*Inactivated pigeon paramyxovirus 1 strain 988M-ca*". ii. It is submitted that previous DSL of firm was valid till 24-Nov-2022 now the firm has submitted new DSL (where address of premises is different) with following details: ***M/s.QAS International,*** ***Address: Plot No.153/155 Mustafa abad Tehsil Kamoki Gujranwala Pakistan.***
Decision: **i. Registration Board referred the case for the detailed comments/recommendations of Animal Husbandry Commissioner regarding need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan.** **ii. The Board also advised firm to apply for change in address of Drug Sale License along with requisite fee.**		
28.	**Name and address of Importer**	**M/s. QAS International, Gujranwala**
	Detail of DSL	Address: Opposite Marian Hotel Near Grace Marque Subhan Ceramics Main GT Road, Gujranwala Valid till: 24-Nov-2022.
	Name and address of Manufacturer	M/s. PHARMAGAL BIO, s. r. o. Murgašova 5 949 01 Nitra Slovak Republic
	Name of exporting country	Slovak Republic
	Brand Name +Dosage Form + Strength	**PHARMAVAC COLUMBI 2** Emulsion for injection for pigeons
	Diary No. Date of R& I & fee	Dy. No.19149 R&I Dated 30-06-2022 Rs. 150,000/- (Slip No 71702695398)
	Composition:	Each dose of vaccine (0.3 mL) contains: Poultry paramyxovirus type1 (strain LaSota), inactivated…… min. 7 log2 HI*. Pigeon herpes virus (strain V298/70), inactivated……. min. 1 log2 VN**. * Haemagglutination-inhibition ** ELIZA units in chicken
	Pharmacological Group	Antiviral
	Finished Product Specification	In house
	Shelf Life	Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
	Document Details	i. Firm has submitted original product specific sole agency agreement valid for 5 years from date of signature i.e. 03.06.2022. ii. Original legalized CoPP (NO. 1167/I/2022) is submitted by the firm.
	Pack size & Price	100doses: Decontrolled
	Reference Regulatory Authority Availability	N/A

	Products already registered in Pakistan	Could not be confirmed
	Remarks of Evaluator:	*i.* Product already registered in Pakistan could not be confirmed with this strain type *"Pigeon herpes virus (strain V298/70)".* ii. It is submitted that previous DSL of firm was valid till 24-Nov-2022 now the firm has submitted new DSL (where address of premises is different) with following details: ***M/s.QAS International,*** ***Address: Plot No.153/155 Mustafa abad Tehsil Kamoki Gujranwala Pakistan***
Decision: **i. Registration Board referred the case for the detailed comments/recommendations of Animal Husbandry Commissioner regarding need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan.** **ii. The Board also advised firm to apply for change in address of Drug Sale License along with requisite fee.**		
29.	**Name and address of Importer**	**M/s. QAS International, Gujranwala**
	Detail of DSL	**M/s.QAS International,** Address/premises situated at: Opposite Marian Hotel Near Grace Marque Subhan Ceramics Main GT Road, Gujranwala Valid till: 24-Nov-2022.
	Name and address of Manufacturer	Manufacturer: M/s. PHARMAGAL BIO, s. r. o. Murgašova 5 949 01 Nitra Slovak Republic
	Name of exporting country	Slovak Republic
	Brand Name +Dosage Form + Strength	**PHARMAVAC PHA** (Emulsion for Injection for pigeons)
	Diary No. Date of R& I & fee	Dy. No. 19150 R&I Dated 30-06-2022 Rs. 150,000/- (Slip No 68098947701)
	Composition:	Each dose of vaccine (0.3 ml) contains: Inactivated Pigeon Paramyxovirus type 1 (PPMV1), strain 988M ≥ 6.9 log2 HIU* Inactivated Pigeon Herpesvirus 1 (PHV1), strain V298/70 ≥ 38.1 EU** Inactivated Fowl Adenovirus type 8 (FAdV-8), strain M2/E ≥ 24.7 EU** * Haemagglutination inhibition units in chicken ** ELISA units in chicken
	Pharmacological Group	Antiviral
	Finished Product Specification	In house
	Shelf Life	24 months
	Document Details	i. Firm has submitted original product specific sole agency agreement valid for 5 years from date of signature i.e. 03.06.2022. ii. Original legalized CoPP (NO. 1168/I/2022) is submitted by the firm.
	Pack size & Price	doses per Vial: Decontrolled
	Reference Regulatory Authority Availability	N/A

	Products already registered in Pakistan	Could not be confirmed.
	Remarks of Evaluator:	i. Product already registered in Pakistan could not be confirmed with this combination and strain types. ii. It is submitted that previous DSL of firm was valid till 24-Nov-2022 now the firm has submitted new DSL (where address of premises is different) with following details: ***M/s.QAS International,*** ***Address: Plot No.153/155 Mustafa abad Tehsil Kamoki Gujranwala Pakistan***
Decision: **i. Registration Board referred the case for the detailed comments/recommendations of Animal Husbandry Commissioner regarding need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan.** **ii. The Board also advised firm to apply for change in address of Drug Sale License along with requisite fee.**		

Miscellaneous/ Deferred Cases:

Following product of M/s We Care, Islamabad was deferred in 332nd meeting of Registration Board as per following details:

Molecule: Heparin Sodium
Evaluator: Ms. Anam Saeed

30.	**Name, address of Applicant / Importer**	**M/s We Care** Address: Flat B-6 Block 12 D 2nd Floor G-8 Markaz Islamabad Pakistan.
	Details of Drug Sale License of importer	**License No: DHO-ISB-930** **Address:** Flat B-6 Block 12 D 2nd Floor G-8 Markaz Islamabad Pakistan **Validity: 19-06-2025** **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s PT PRATAPA NIRMALA JL. INDUSTRI VI TANGERANG 15135-INDONESIA
	Name, address of manufacturer(s)	M/s PT PRATAPA NIRMALA JL. INDUSTRI VI TANGERANG 15135-INDONESIA
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No.RG.01.05.32.321.05.22.3865) dated 17-05-2022 valid till 17-05-2024 issued by National Agency of Drug and Food control Jl. Percetakan Negara No. 23, JAKARTA-INDONESIA. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of 5's x 5mL vial in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized LOA dated 26-04-2022 and legalized distribution agreement dated 21-04-2022 (signed by both firms) valid for five years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5109 (R&I) dated 21-02-2023
	Details of fee submitted	Deposit Slip # 8167115543 of PKR. 150,000/- dated 22-02-2023
	The proposed proprietary name / brand name	**Inviclot Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Heparin Sodium……5000IU
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	-
	Proposed Pack size	5's x 5mL vial
	Proposed unit price	Not Provided
	Shelf Life	24 months
	Storage Conditions	Store Below 30°C
	The status in reference regulatory authorities	-
	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow of manufacturing process, analytical procedures, justification of specification.
	Name, address of drug substance manufacturer	**Company:** Adeste Indústria de Produtos Animais LTD **Address:**Rua Paes Leme, 524, 6º andar Grupo 63 - CEP 054 24 904 Pinheiros – São Paulo – Brazil Phone: 55 11 30975544 Fax: 55 11 30975545
	Module-III Drug Substance:	Firm has submitted drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures, batch analysis and justification of specifications.
	Stability Studies of Drug Substance	Firm has provided stability studies of 3 batches of drug substance.
	Module-III Drug Product:	Firm has summarized data of drug product including its composition, manufacturing process, control of drug product, process verification, specifications, batch analysis, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods
	Container closure system of the drug product	Heparin Sodium 5000 units/mL is supplied as 5-mL volume injection, in a vial made of type I glass and packed in a box. Each container bears printed information concerning product

		characteristics (name, active ingredient, pharmaceutical form, strength) and batch characteristics (batch number and expiration date). The suitability of the primary packaging is confirmed by the Certificate of Quality from the vial manufacturer. Incompatibilities with primary packaging or excipients used were not observed; however, during the stability study there were not any particles leaked and the parameters tested remained within the requirements.
	Stability study data of drug product	Firm has submitted stability study data of 03 batches. The accelerated stability studies are conducted at 40 ± 2^0C/75%RH±5% for 6 months. The real time stability studies are conducted at 30 ± 2^oC/75%±5RH for 36 months for one batch. While at 30 ± 2^oC/60%±5RH for other two batches. Bacterial Endotoxin test and sterility test are performed at 0,6,12,24 months in real time stability studies while at 0 and 6 months in accelerated stability studies.
	Remarks of Evaluator	The firm has not performed testing as per official pharmacopeia.
	Decision of RB in 331st meeting	*Registration Board deferred the case for submission of specifications, analytical procedures and COAs as per official pharmacopoeia.*
	Decision of RB in 332nd meeting	*The case was discussed in 331st meeting of Registration Board. No response received from the firm. Case was deferred for clarification by the firm.*
	Remarks of Evaluator	The firm has submitted analytical methods and Certificate of analysis as per British Pharmacopoeia. However, the test of Zone electrophoresis has not been performed for Identification as mentioned in BP monograph.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of analytical method and certificate of analysis depicting Identification test by Zone electrophoresis as mentioned in BP monograph.		

Molecule: Nivolumab
Evaluator: Mr. Muhammad Kashif

The following products of M/s Himmel Pharmaceuticals (pvt) Ltd Lahore was deferred in 324th meeting of Registration Board as per following details.

31.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-0016174D **Address:** 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan **Address of go-down: N/A** **Validity: 06-02-2022** **Status:** License to sell drugs by way of Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited **Plant address**: Kathali Bhaluka Mymensingh **Bangladesh.** **ffice Address**: 9/B/2 Toyenbee Circular Road Motijheel, Dhaka 1223 Bangladesh
	Name, address of manufacturer(s)	-do-
	Name of exporting country	Bangladesh

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3355) issued on 4-June-2020 **by** Directorate General of Drug Administration Ministry of Health & Family welfare Government of the people's republic of Bangladesh. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:2years)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization dated 02-06-2020 from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register & sell their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	y. No32920 Dated 10.12.2020, Dy. No.8733 Dated 05.04.2022, y. No.13612 Dated 06.06.2022
	Details of fee submitted	Rs. /- 50000 Dated 19.11.2020
	The proposed proprietary name / brand name	Nivolunix 40 Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains Nivolumab INN….40mg
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agents (Anti-cancer), Monoclonal Antibodies
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack Size: 1's
	Proposed unit price	Retail price As per SRO
	Shelf Life	24 months
	Storage Conditions	2 ^{O}C -8^{O}C
	The status in reference regulatory authorities	PDIVO (NIVOLUMAB 40mg/4mL single dose vial) | BLA #125554 | BRISTOL MYERS SQUIBB in USFDA
	For generic drugs (me-too status)	ot available in Pakistan

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at 25±2°C for 10 days, at 5 ±3 °C for 6months & ≤-30 °C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted specification & in-house analytical method along with Analytical method validation studies for the applied product.
	Container closure system of the drug product	Nivolunix 40mg injection is provided in 5mL clear glass vial (USP type-I glass) 20 mm rubber stopper, type -1 and 20mm Flip off seal with red color top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 commercial batches. The accelerated stability study data is conducted at 40° C ± 2° C & 75% ± 5% RH for 6 months. The real time stability study data is conducted at 2 ^{O}C -8^{O}C for 24 months.
	Module-IV	**Pharmacology studies:** The binding of product to human CD279 (programmed cell death 1, PD-1): • Effects on interaction between PD-1 and PD-1 ligands using the PD-1/CHO cell line and biotin-labeled recombinant human PD-L1- Fc and PD-L2-Fc fusion proteins. • Effect on immunoreactivity (on alloantigen-induced T-cell activation, antigen-specific T cell reactivity using Cynomolgus monkeys) • Activity against malignant tumors in mice with malignant melanoma B16F10 cells.

		• Secondary pharmacodynamics (antibody-dependent cell-mediated cytotoxicity) • Safety pharmacology (Effects on the central nervous system, Effects on the cardiovascular system, Effects on the respiratory system) **Pharmacokinetic studies:** (Analytical procedures-assay, antibody assay, Single-dose administration, Repeated-dose administration) **Toxicology studies:** Single-dose toxicity using cynomolgus monkeys, Repeated-dose toxicity in cynomolgus monkeys, Extended study of pre- and postnatal development in cynomolgus monkeys, Cross-reactivity studies, Four-week repeated intravenous dose toxicity study with ipilimumab coadministration in cynomolgus monkeys) **Note:** The submitted clinical trial data is from bulk manufacture not from the finish product manufacter.
	Module-V	**Phase I study:** • An open-label study to investigate the pharmacokinetics (PK) in 17 patients with advanced solid tumors resistant to conventional therapies. **Phase II study:** An open-label study to investigate the PK and other endpoints in 35 patients. **Phase III study:** A Phase III trial to compare the efficacy & safety of FX02 and Opidivo (Nivolumab) injection in patients with advance NSCLC who had received prior platinum-based chemotherapy. **Note:** The submitted clinical trial data is from bulk manufacture not from the finish product manufacturer.
32.	Name, address of Applicant / Importer	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan Address of go-down: N/A Validity: 06-02-2022 Status: License to sell drugs by way of Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh. Office Address: 9/B/2 Toyenbee Circular Road Motijheel, Dhaka 1223 Bangladesh
	Name, address of manufacturer(s)	-do-
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original legalized COPP (DA/6-110/2016/3355) issued on 4-June-2020 by Directorate General of Drug Administration Ministry of Health & Family welfare Government of the people's republic of Bangladesh. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:2years)

	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization dated 02-06-2020 from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register & sell their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No32921 Dated 10.12.2020, Dy. No.8733 Dated 05.04.2022, Dy. No.13612 Dated 06.06.2022
	Details of fee submitted	Rs. /- 50000 Dated 19.11.2020
	The proposed proprietary name / brand name	Nivolunix 100 Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains Nivolumab INN….100mg
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agents (Anti-cancer), Monoclonal Antibodies
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack Size: 1's
	Proposed unit price	Retail price As per SRO
	Shelf Life	24 months
	Storage Conditions	2^0C -8^0C
	The status in reference regulatory authorities	OPDIVO (NIVOLUMAB 100mg single dose vial) | BLA #125554 | BRISTOL MYERS SQUIBB in USFDA
	For generic drugs (me-too status)	Not available in Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at 25±2 °C for 10 days, at 5 ±3 °C for 6months & ≤-30 °C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted specification & in-house analytical method along with Analytical method validation studies for the applied product.
	Container closure system of the drug product	Nivolunix 40mg injection is provided in 5mL clear glass vial (USP type-I glass) 20 mm rubber stopper, type -1 and 20 mm Flip off seal with red color top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 commercial batches. The accelerated stability study data is conducted at 40° C ± 2° C & 75% ± 5% RH for 6 months. The real time stability study data is conducted at 2 OC -8OC for 24 months.
	Module-IV	Pharmacology studies: The binding of product to human CD279 (programmed cell death 1, PD-1): • Effects on interaction between PD-1 and PD-1 ligands using the PD-1/CHO cell line and biotin-labeled recombinant human PD-L1- Fc and PD-L2-Fc fusion proteins. • Effect on immunoreactivity (on alloantigen-induced T-cell activation, antigen-specific T cell reactivity using Cynomolgus monkeys) • Activity against malignant tumors in mice with malignant melanoma B16F10 cells. • Secondary pharmacodynamics (antibody-dependent cell-mediated cytotoxicity) • Safety pharmacology (Effects on the central nervous system, Effects on the cardiovascular system, Effects on the respiratory system) Pharmacokinetic studies: (Analytical procedures-assay, antibody assay, Single-dose administration, Repeated-dose administration) Toxicology studies: Single-dose toxicity using cynomolgus monkeys, Repeated-dose toxicity in cynomolgus monkeys, Extended study of pre- and postnatal development in cynomolgus

		monkeys, Cross-reactivity studies, Four-week repeated intravenous dose toxicity study with ipilimumab coadministration in cynomolgus monkeys) Note: The submitted clinical trial data is from bulk manufacture not from the finish product manufacter.
	Module-V	**Phase I study:** • An open-label study to investigate the pharmacokinetics (PK) in 17 patients with advanced solid tumors resistant to conventional therapies. **Phase II study:** An open-label study to investigate the PK and other endpoints in 35 patients. **Phase III study:** A Phase III trial to compare the efficacy & safety of FX02 and Opidivo (Nivolumab) injection in patients with advance NSCLC who had received prior platinum-based chemotherapy. Note: **The submitted clinical trial data is from bulk manufacture not from the finish product manufacturer.**

Bio-similarity studies:	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	**a) Primary Structure:** i. Amino acid sequence by LC-MS & MS/MS ii. N-terminal sequence by LC-MS. iii. C-terminal lysine by LC-MS. iv. N-glycosylation site by Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) **b) Secondary Structure & high order Structure** i. Intact mass by LC-MS ii. Disulfide bond by LC-MS iii. Free thiol (Ellman's) iv. Circular Dichroism (Secondary Structure) by Far spectrogram. v. Thermostability by differential fluorimetry (DSF) **c) Heterogenicity** i. Glycan by LC-MS ii. Heterogenicity of glycosylation by FLD-HPLC iii. Isoelectric point by CIEF iv. Charge variant (CEX-HPLC
Biological Activity	Biological activity by: • PD-I binding activity by ELISA
Impurities	• Purity by SEC-HPLC • Purity by CE-SDS • Protein A by ELISA • DNA residual by qPCR • Host cell protein by ELISA
Stability Studies	Stability studies are provided.
Non-clinical Studies	Primary pharmacodynamics by: • Binding to PD-I • Inhibitory effect against binding of PD-I to PD-L1 or PD-L2

	• One month repeated doses toxicity study in monkeys • Six months repeated doses toxicity study in monkeys
Clinical Studies	Comparative clinical study has not been submitted.

Evaluation by BE&R:

#	Decision of 329th meeting	Response by the firm
1.	Regulatory status of products in various countries where the bulk of the product is exported.	**i.** The Firm has submitted the registration certificate of the product Nivolunix 40 and 100mg Injection manufactured by M/s Beacon Medicare Limited, Bangladesh. **ii.** The Firm has submitted the registration certificate issued No.DV/X 09452/11/21 of the product Nivolunix 40 & 100mg Injection manufactured by M/s Beacon Medicare Limited, Bangladesh, issued by Ministry of Health Care of Republic of Uzbakistan. **iii.** The Firm has submitted the registration certificate vide No. H2021/CTD8547/18726 and Certificate vide No. H2021/CTD8548/18707 for the product Nivolunix 40 & 100mg Injection manufactured by M/s Beacon Pharmaceuticals, Bangladesh, issued by Ministry of Health, Pharmacy and Poisons Board, Kenya.
2.	Publication of clinical trial in any peer reviewed journal.	Oncology & Cancer Case Reports Vol. 9, Issue 04, 01-02 by Shane Ali Dungersi*, Vijayakumar Narayanan and James Mbogo Department of Clinical Oncology, Dr. Vj's Oncology Associates Pvt Ltd., Nairobi, Kenya
3.	Data of Periodic Safety Updated report of applied formulation marketed in Bangladesh.	PERIODIC SAFETY UPDATE REPORT (PSUR), Bangladesh, report date 1st May, 2021
4.	Differential fee of Rs. 100,000 /- for each product.	Not Submitted.

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product i.e. Nivolunix 40mg Injection **and** Nivolunix 100mg Injection **subject to compliance of current Import Policy for finished drugs. The firm shall submit the differential fee before issuance of registration letter.**

Molecule: Pembrolizumab
Evaluator: Mr. Muhammad Kashif

33.	**Name, address of Applicant / Importer**	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block ''C'', Faisal Town Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address: 793-D, Block-C, Faisal Town Lahore Address of Godown: NA Validity: 06.Feb.2024 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali ,Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel

		Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# DA/6-110/2016/3353 issued on 04-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted (Certificate No. DA/6-110/06/4950).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No32920 Dated 10.12.2020 Dy. No.8733 Dated 05.04.2022, Dy. No 1531 Dated 17.01.2023
	Details of fee submitted	PKR: 50,030/- Date: 10-12-2021
	The proposed proprietary name / brand name	Pembroxim Injection 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4 ml contains Pembrolizumab INN….100mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	1 s
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Keytruda 100mg
	For generic drugs (me-too status)	NA

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Keytruda (Merck sharp & Dohme, B.V Netherlands) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type 1 Glass Vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40ºC±2ºC and 75%±5% RH for 6 months. Real time stability studies conducted at 2 ºC -8 ºC and 65% ± 5% for 24 months
Bio-similarity studies:		
WHO Bio-similarity guidelines	**Data submitted by the firm**	

Quality Comparison Physicochemical characterization	**a) Primary Structure:** i. Amino acid sequence by LC-MS & MS/MS ii. N-terminal sequence by LC-MS. iii. C-terminal lysine by LC-MS. iv. N-glycosylation site by Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) **b) Secondary Structure & high order Structure** i. Intact mass by LC-MS ii. Disulfide bond by LC-MS iii. Free thiol (Ellman's) iv. Circular Dichroism (Secondary Structure) by Far spectrogram. v. Thermostability by differential fluorimetry (DSF) **c) Heterogenicity** i. Glycan by LC-MS ii. Heterogenicity of glycosylation by FLD-HPLC iii. Isoelectric point by CIEF iv. Charge variant (CEX-HPLC
Biological Activity	Biological activity by: • PD-I binding activity by ELISA
Impurities	• Purity by SEC-HPLC • Purity by CE-SDS • Protein A by ELISA • DNA residual by qPCR • Host cell protein by ELISA
Stability Studies	Stability studies are provided.
Non-clinical Studies	Primary pharmacodynamics by: • Binding to PD-I • Inhibitory effect against binding of PD-I to PD-L1 or PD-L2 • One month repeated doses toxicity study in monkeys • Six months repeated doses toxicity study in monkeys
Clinical Studies	Comparative clinical study has not been submitted.

Evaluation by BE&R
Evaluation by BE&R:

#	Decision of 329th meeting	Response by the firm
1.	Regulatory status of products in various countries where the bulk of the product is exported.	i. The Firm has submitted the registration certificate of the product Nivolunix 40 and 100mg Injection manufactured by M/s Beacon Medicare Limited, Bangladesh. ii. The Firm has submitted the registration certificate vide No. H2021/CTD8470/18741 for the product Pembroxim 100mg Injection manufactured by M/s Beacon Pharmaceuticals, Bangladesh, issued by Ministry of Health, Pharmacy and Poisons Board, Kenya.
2.	Publication of clinical trial in any peer reviewed journal.	A Sci Technol Journal (Local Journal), Oncology & Cancer Case Reports Vol. 5, Issue 12, 1000266 by Shane Ali Dungersi*, Vijayakumar Narayanan and James Mbogo Department of Clinical Oncology, Dr. Vj's Oncology Associates Pvt Ltd., Nairobi, Kenya having following Abstract:

		"Historically, advanced and metastatic non-small cell lung cancer had dismal prognosis. These patients were subjected to best supportive care which included, inter alia, symptomatic management and advance care planning to get the best out of whatever time that is remaining for them. However, the past decade has seen important advances in treatment and diagnosis which have translated into improved survival outcomes in such cases. The Introduction of targeted therapy and immunotherapy for selected patients had dramatically changed the outcome of such patients, both in life expectancy and quality of life." with following **Conclusion**: **"***With the advent of newer therapeutic agents, there is a true paradigm shift in cancer therapy especially in late stage. Improvements in survival outcome and good quality of life can be expected. Appropriate selection of cytotoxic drugs, systemic targeted therapy, immunotherapy is the key in reaching this goal. There should be an attitudinal change in addressing the issues of a patient with advanced disease.***"**
3.	Data of Periodic Safety Updated report of applied formulation marketed in Bangladesh.	PERIODIC SAFETY UPDATE REPORT (PSUR), Bangladesh, report date 1st May, 2020: **Conclusion:** **"***Pembrolizumab increased overall survival (OS) compared to chemotherapy, with a better safety profie in this pooled analysis of older patients with advanced NSCLC and PD-L1-positive tumors. Pembrolizumab patient outcomes at 275 years of age were equivalent to those in the total populations in the different studies***"**
4.	Differential fee of Rs. 100,000 /- for each product.	Not Submitted.

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit the differential fee before issuance of registration letter.

Case: Request for change of Brand name of TALTZ Injection 80mg/ 1mL of M/s Eli Lilly Pakistan (Pvt) Ltd.

Following product of M/s Eli Lilly Pakistan (Pvt) Ltd, Karachi was approved in 297th meeting of Registration Board as per following details:

Molecule: Ixekizumab

Evaluator: Ms. Haleema Shareef

Sr. No.	Name of Manufacturer	Brand Name & Composition	Pack Size	Decision of RB in 297th Meeting
34.	M/s Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285, USA	TALTZ Injection 80mg/ 1mL Each autoinjector pre-filled pen contains: Ixekizumab: 80mg/mL Shelf Life: 24 months(5^0C)	1's Prefilled Pen (Autoinjector)/ As per SRO	Keeping in view valid legalized CoPP and approval of USFDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs

The product is not yet registered as Federal Government has not yet notified the price of above product. Now the firm has submitted the application for change in brand name as per following details:

Already Approved Brand Name	Newly Applied Brand Name
Taltz Injection 80mg/ 1mL	Aryzing Injection 80mg/1mL

The application of the firm is evaluated as per SOPs of 283rd meeting of Registration Board:

Sr.	SOPs approved in 283rd Meeting	Documents submitted by the firm
i.	Application with required fee as per relevant SRO (in case of similarity/ resemblance with drug, fee will note be required).	Submitted
ii.	Copy of registration letter and las renewal status.	Not Applicable
iii.	Justification for proposed change.	Submitted
iv.	Information regarding previous change of brand name since registration do drug.	Not Applicable
v.	Details (batch number, date of manufacture, quantity and stock position) regarding last batch imported.	Not Applicable
vi.	An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/ similarity with already change immediately. Moreover, no case is pending at any forum/ court of law regarding this matter.	Submitted
vii.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new brand name or Original and legalized GMP certificate of new brand name with free sale certificate from regulatory body of country of origin.	Submitted
viii.	Undertaking that the provided information/ documents are true/ correct.	Submitted

Registration Board in its 307th meeting authorized its Chairman for approval of change in brand name of registered drugs. Although the instant product is not yet registered, however is already approved by the Board for registration.

Therefore, the case was processed to Chairman Registration Board for perusal /approval of change in brand name from Taltz Injection to Aryzing Injection wherein he advised to process case after fixation of price.

Now the firm requested to change brand name from Taltz to **Aryzing** for Pakistan before going in Pricing. This is due to the Company's internal recommendation based on different brand name assigned to different countries for marketing and commercial reasons.

The case is hereby submitted for consideration of the Board, Please.

Decision: Registration Board deferred the case for clarification from the firm whether it is innovator product or otherwise. The firm is required to submit its response with 07 days,

Molecule: Avian Influenza (Vet)
Evaluator: Ms. Anam Saeed

Following product of M/s Saadat International, Lahore was deferred in 329th meeting of Registration Board as per following details:

35.	**Name and address of Importer**	**M/s Saadat International,** 117 Habitat Flat Shadman II, Jail Road, Lahore.
	Detail of DSL	**M/s Saadat International:** Address: 117 Habitat Flat Shadman II, Jail Road, District Lahore Valid till: 12-Jun-2022
	Name and address of Manufacturer	**Marketing Authorization Holder:** M/s Boehringer Ingelheim Vetmedica GmbH Binger Strabe 173, 55216 Ingelheim am Rhein, Germany.
		Manufacturer of Drug: M/s Boehringer Ingelheim Animal Health Rue De L aviation, 69800 ST PRIEST -France
	Name of exporting country	France

	Brand Name +Dosage Form + Strength	**Gallimune H9+ND**
	Diary No. Date of R& I & fee	Dy. No. 19297 R&I Dated 09-07-2021 Rs. 150,000/ (Slip No. 07658493298)
	Composition	Each 0.3 mL dose contains: Inactivated Avian Influenza Virus, H9N2 (Iraq)strain at least7log2HI.U. Inactivated Newcastle Disease Virus, Ulster 2C strain at least 16HI.Ufr
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's Specifications
	Shelf Life	24 months----(2-8^{o}C)
	Document Details	**GMP certificate (Original Legalized):** Certificate No. 20/265668 Issued to: M/s Boehringer Ingelheim Animal Health Rue De L aviation, 69800 ST PRIEST-France (Manufacturer) Issued by: French agency for veterinary medicinal products. Validity: Three years from the date of inspection (conducted on February 17th 2020 to February 20th 2020). **Sole Agency Agreement:** **Boehringer Ingelheim Vetmedica GmbH** (the marketing authorization holder of the product), a company incorporated under the laws of Germany, with its principal office at Binger Strabe 173, 55216 Ingelheim am Rhein, Germany (BIV GmbH) herewith appoints; Saadat International 117 Habitat Flat Shadman II Jail Road Lahore our sole agent in Pakistan for Gallimune H9+ ND, the product is manufactured and supplied to Saadat International by BIV GmbH affiliated company: Boehringer Ingelheim Animal Health France. **COPP (Original Legalized):** Certificate No. 20-268470
	Pack size	300mL bottle
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Gallimune 208 ND+Flu H9 M.E. Emelsion for Injection. [Each Dose of Vaccine Contains: - Inactivated Avian Influenza Virus H9N2 Strain Minimum Titer Before Inactivation...108 EID_{50}. Inactivated Newcastle Disease Virus, Ulster 2c Strain Minimum Titer Before Inactivation 1068 EID_{50}].

	Remarks of Evaluator	In response to this division's letter dated 12th January 2022 applicant has submitted following documents: Field trial data. Finished Product Specifications: Manufacturer. Following justification regarding this statement on the COPP that product is not licensed to be placed in the market of country of origin is required. "Gallimune H9+ND is not licensed to be placed in the France market because avian influenza caused by H9N2 subtype is not present in poultry farms of this country. Therefore:
		No Free certificate could be obtained for any H9 vaccine. All the H9 vaccines manufactured in France are for exportation purpose only for the countries that have the H9 as endemic disease, so the authority can only provide certificate of origin and/or Certificate of Pharmaceutical product". Following documents are still required: Finished product specifications in light of 267th RB meeting.
	Previous Decision (M316)	Registration Board deferred the product for submission of evidence of availability of formulation in reference regulatory authorities.
	Evaluation by BE&R Division	*The firm has submitted that Gallimune H9+ND is not registered in reference regulatory authorities (same as all the vaccines contain H9N2 formulations) because avian influenza caused by the H9N2 subtype is not present in poultry farms of these countries.*
	Decision of Registration Board in its 320th meeting	Registration Board deferred the product for submission of evidence of availability of formulation in country of origin or in any other reference regulatory authorities.
	Evaluation of DBE&R	Firm has submitted following: The reason for its non-availability in the country of the origin and countries of the reference regulatory authorities is as under; 1. It is not registered in the country of origin or countries of the reference regulatory authorities because the low pathogenic the avian influenza LPAAI subtype H9N2 is not present in the poultry birds in these countries. 2. The isolates of H9N2 is derived mainly from Middle Eastern lineage not from European lineage which is mainly in the wild birds (no vaccination). 3. The Avian Influenza H9N2 lineage G1-h9.4.2 viruses are widely distributed and endemic poultry in Pakistan, Bangladesh, regions of India, Afghanistan, Nepal, Egypt, Saudi Arabia and Israel. Main Points to support the claim for the safety, quality & efficacy of the drug/vaccine:- • However, I would like highlight that the said product is a quality vaccine manufactured by M/S Boehringer Ingelheim, one of the leading animal health companies manufacturing vaccines and Pharmaceutical products at its sites in USA, France and Italy which are fully complying the USDA, EU GMP standards. The said product is

		manufactured at Boehringer Ingelheim's French site which is fully compliant with the EU and WHO GMP standards. • We have already submitted the GMP certificate and COPP which shows the full compliance status. • Kindly refer to the relevant parts of Quality; safety and efficacy of the Technical Dossier of the vaccine already submitted which shows the full compliance of the EU GMP standards during whole of its manufacturing process. • I would also like to add that one of our already registered vaccine Gallimune 208(Reg. No: 034559) since which has the same composition of Gallimune ND+H9 and has been used by the poultry farmers to control avian influenza H9 with its proven quality, efficacy and safety. • *The Gallimune ND+H9, the vaccine under registration has the same composition except that the subtype (strain) 0f the H9N2 has been upgraded to match the current epidemiological data/prevalence of the disease in our region.* • I would also like to bring to your attention that a number of vaccines with the same composition have already been granted registration which are produced in countries of non reference regulatory authorities such as China, Korea and Egypt.
	Decision of Registration Board in its 329th meeting	*Registration Board referred the case to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the applied strains in Pakistan.*
	Comments of Ministry of National Food Security & Research, Islamabad	**Gallimune H9+ND vaccines are already available in Pakistan. However, this vaccine has H9N2 (Iraq) strain. Genetic similarity and antigenic similarity with recently H9N2 reported strains indicate that this vaccine would give good protection in Pakistan. Vaccine may be recommended with post use monitoring.**
Decision: On the basis of documents/information/data and keeping in view the comments of Ministry of National Food Security & Research, Registration Board approved the product subject to compliance to current import policy of Finished Drugs. The M/o NFS&R shall conduct post marketing surveillance, as per recommendation.		

Molecule: Recombinant Subunit Vaccine (Vet)
Evaluator: Ms. Anam Saeed

Following product of M/s Uranus Biotech (Private) Limited, Islamabad was deferred in 313th meeting of Registration Board as per following details:

36.	**Name of Importer**	**M/s Uranus Biotech (Private) Limited,** office No. 112, First Floor, Arooj Arcade, Sector F-10 Markaz, Islamabad
	DSL details	License No. DSL-839-ICT/2013 dated 26-02-2018 valid till 25-02-2018

	Name of Manufacturer	M/s Chongqing Auleon Biologicals Co. Ltd., The Fourth Branche Road, Banqiao Industrial Park, Rongchang District, Chongqing, P.R. China.
	Brand Name +Dosage Form + Strength	Echinococcosis Recombinant Subunit Vaccine (Sheep & goats)
	Composition	Each dose contains: Eg95 antigen……50µg
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	12 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 10322, 29965, 7518& 3293 Dated: 20-03-2018, 06-09-2018, 20-02-2019&11-04-2019 Rs. 100000/- dated 14-03-2018
	Demanded Price / Pack size	1's Vial (40 doses)/ De-controlled.
	General documentation	Valid legalized GMP certificate No. (2016) GMP 23013 dated 21-12-2016 valid till 20-12-2021 Legalized Free Sale Certificate dated 23-11-2017 valid till 22-11-2018.
	Decision of RB in 291st meeting	*Registration Board deferred the case for submission of evidence of availability of above formulation in reference regulatory authorities.*
	Remarks of evaluator	The firm has now submitted that the product is only registered in Kyrgyzstan and not in any reference regulatory authority. Moreover, the firm has submitted article regarding prevalence of Echinococcosis in Pakistan instead of availability of formulation in reference countries.
	Decision of RB in 313th meeting	*Registration Board referred the case to Animal Husbandry Commissioner for comments regarding the need of vaccine, prevalence of disease (Echinococcosis) and immunological relevance of Eg95 antigen/strain in Pakistan.*
	Comments of Ministry of National Food Security and Research	The disease is prevalent in Pakistan. Successful research trials around the world indicate it would provide good protection in the country. It may be recommended with post use monitoring.
Decision: On the basis of documents/information/data and keeping in view the comments of Ministry of National Food Security & Research, Registration Board approved the product subject to compliance to current import policy of Finished Drugs. The M/o NFS&R shall conduct post marketing surveillance, as per recommendation.		

Exemption Cases

Case: Grant of Exemption of Inspection to M/S. Mustafa Brothers based on EUDRA GMP for Products Pulmovac, Antox 9, Leptogard.

Evaluator: Ms. Haleema Shareef

Following products; Pulmovac, Antox 9, Leptogard of M/s. Mustafa Brothers are approved in 295th Registration Board meeting as per following details:

Sr. No.	Importer Name & Manufacturer of Drug:	Brand Name & Composition	Decision of 295th Registration board meeting:
37.		**Pulmovac**	

	M/s Mustafa Brothers P-186-D, People Colony No. 1, Faisalabad M/s. Federal state enterprise "Stavropol biofactory" Stavropol city, 18 Biological street, 355019, Russia.	Inactivated emulsified vaccine against pasteurellosis of ruminant animal	Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The panel of inspectors shall verify the authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by regulatory body of country of origin. The registration letter shall be issued after said verification.
38.		**Antox 9** Inactivated vaccine against clostridiosis of agricultural animals	
39.		**Leptogard** Inactivated lyophilized vaccine against leptospirosis of animals	

It is submitted that firm has claimed exemption of inspection of manufacturer abroad as manufacturing facility abroad has EUDRA GMP. However, the title of company on EUDRA GMP was different than in meeting minutes for this the firm has submitted clarification from the director of firm that the difference in title of firm is due to translation from Russian to English language, the difference is recorded in below mentioned table:

Title of firm in meeting minutes	Title of firm in EUDRA GMP	Google translation from Russian to English
M/s. Federal state enterprise "Stavropol biofactory" Stavropol city, 18 Biological street, 355019, Russia.	***M/s. FKP Stavropolskaya Biofabrika. 18, Biologitcheska str, Stavropol, 355019, Russian Federation***	M*/s. FKP Stavropol Biofactory. 18, Biological str, Stavropol, 355019, Russian Federation*

To verify the claim of firm name and address of company on EUDRA GMP is translated from Russian to English via google translator which is recorded in last column of above table and observed that name and address of the company of EUDRA GMP is similar to that what mentioned in meeting minutes with the exception of following difference:

Title of firm in meeting minutes	Title of firm in EUDRA GMP	Google translation from Russian to English
M/s. Federal state enterprise	***M/s. FKP***	*M/s. FKP*

For this difference firm has submitted a clarification: In Russian FKP: F-ФепраπebHoe (Ф-F "in English Federal), (K-Ka3eHHoe in English State), (P-IIpeπHpNRTNE (II-P << in English Enterprise").and inspection report conducted by authority of German where M/s. Federal state enterprise (FKP) is written.

In the light of clarification provided by firm, inspection report conducted by authority of German submitted by the firm and translation via google translator from Russian to English Chairman Registration Board granted exemption of inspection of manufacturing facility abroad.
The case is hereby placed for information and ratification by the Board.

Decision: Registration Board noted the information and ratified the case.

40. Exemption of Drugs (Labelling and Packaging) Rules, 1986 and permission for Local Printing of Labelling Particulars of imported Registered Biological Product by M/s Lab Diagnostic Systems.

Evaluator: Ms. Anam Saeed

Registration Board in its 330th meeting considered the request of the firm M/s Lab Diagnostic Systems for exemption of Drugs (Labelling and Packaging) Rules, 1986 and permission for Local Printing of Labelling Particulars of imported Registered Biological Product and decided as under;

*"Registration board acceded to the request of the firm for one time import permission of **Vinox 40mg** (Enoxaparin sodium), Batch No. A1F2110V3, Mfg date: 26-02- 2023, Exp date: 31-01-2026 and **Vinox 60mg**, Batch No. A1A0310K1, Mfg date: 23-02-2023, Exp date: 31-01-2026 and local printing of MRP, Registration*

No. and other parameters, as per Drugs (Labelling & Packing) Rules, 1986 before sale in market, at the premises of M/s Novamed Pharmaceuticals, 28-km Ferozepur Road, Lahore having DML # 000590 subject to the submission of Fee required for exemption".

Remarks of BE&R:

During processing of the case for issuance of letter, it was noted that complete parameters are not defined by the firm which are to be printed locally. Upon asking, the firm informed that the parameters MRP, Registration Number and **Brand name** will be printed locally.

As in previous decision of the Registration Board, the parameter, brand name is not mentioned so the case is hereby placed before the board for consideration, as advised by the Chairman Registration Board.

Decision: "Registration board acceded to the request of the firm for one time import permission of registered durgs Vinox 40mg (Enoxaparin sodium), Batch No. A1F2110V3, Mfg date: 26-02- 2023, Exp date: 31-01-2026 (Quantity: 19,860 PFS) and Vinox 60mg, Batch No. A1A0310K1, Mfg date: 23-02-2023, Exp date: 31-01-2026 (Quantity: 39,940 PFS) in its standard packs and local printing of MRP, Registration No. and Brand name, as per Drugs (Labelling & Packing) Rules, 1986 before sale in market, at the premises of M/s Novamed Pharmaceuticals, 28-km Ferozepur Road, Lahore having DML # 000590."

Deputy Director	**Designated No.**	**No. of Cases**
Mr. Muhammad Kashif	DD-I	04
Total		04

New/ Under Registration Cases:

Priority / Out of Queue consideration of Heparin & Enoxaparin Injections

DRAP Authority in its 144th meeting held on 26-08-2022 while considering the shortage of Heparin & Enoxaparin injections decided as follows:

"*The Authority, as a one-time exercise, approved out of queue consideration of submitted registration applications of following drugs in order to ensure their smooth and continuous supply in the market:*

Paracetamol (Tablets, lnfusion and Syrup / Suspension)

Albumin bound Paclitaxel lnjection

Heparin and Enoxaprin lnjection

*PE&R and BE&R Divisions are advised to process the cases of abovementioned drugs without waiting for formal approval of minutes.****"***

DRAP Authority in its 165th meeting held on 20-07-2023 approved out of queue consideration of submitted registration applications of following drugs

Heparin, Anti-D, Streptokinase Injection

DRAP Authority in its 178th meeting held on 23-01-2024 approved out of queue consideration of submitted registration applications of following drugs

Heparin, Anti-D, Streptokinase Injection and Insulin

Imported Heparin Injection from non-Reference countries:

Molecule: Heparin Sodium

Evaluator: Mr. Muhammad Kashif

41.	me, address of Applicant / Importer	**s Safemed Technologies**, T, 3, 2nd Floor, Retoon Plaza, Mini Market, Sector G-15/1, Islamabad.
	tails of Drug Sale License of importer	ense No: DHO-ISB-333 Address: T, 3, 2nd Floor, Retoon Plaza, Mini Market, Sector G-15/1, Islamabad. idity: 24-08-2024 Status: Distribution License

	me and address of marketing authorization holder (abroad)	s Hebei Changshan Biochemical Pharmaceutical Co. Ltd., No. 71 Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone (050800), China
	me, address of manufacturer(s)	s Hebei Changshan Biochemical Pharmaceutical Co. Ltd.,
		. 71 Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone (050800), China
	me of exporting country	na
	tail of certificates attached (CoPP, Free sale certificate, GMP certificate)	m has submitted legalized CoPP (No. Hebei 20210440) dated 15-10-2021 valid till 14-10-2023 issued by Hebei Province Drug Administration. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of the product in country of origin.
	tails of letter of authorization / sole agency agreement	m has submitted product specific Letter of Authorization from Enterprise Legal Person of M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd., According to the letter, the firm *M/s Hebei Changshan* exclusively authorizes "Safemed Technologies" to register, sale and quote the product. The letter was issued on 06-04-2022 and valid till 30-03-2025.
	tus of the applicant	☐ Manufacturer mporter ☐ Is involved in none of the above (contract giver)
	tus of application	☐ New Drug Product (NDP) Generic Drug Product (GDP)
	nded use of pharmaceutical product	Domestic sale ☐ Export sale ☐ Domestic and Export sales
	imported products, specify one the these	Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	. No. and date of submission	. No. 14234 (R&I) Dated 13-06-2022
	tails of fee submitted	150,000/- dated 02-06-2022
	e proposed proprietary name / brand name	taparin Injection
	ength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	ch vial (5mL) contains: parin Sodium..... 25000IU
	sage form of applied drug	ection
	rmacotherapeutic Group of (API)	ticoagulant
	ference to Finished product specifications	Specifications
	posed Pack size	Vials
	posed unit price	1600/Vial
	elf Life	Years

	rage Conditions	±2°C/60±5% RH
	e status in reference regulatory authorities	parin Panpharma of M/s Panpharma, France.
	generic drugs (me-too status)	xcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	dule-II (Quality Overall Summary)	m has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and
		tification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	me, address of drug substance manufacturer	s Hebei Changshan Biochemical Pharmaceutical Co. Ltd., No. 71 Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone (050800), China
	dule-III Drug Substance:	m has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	bility Studies of Drug Substance (Conditions & duration of Stability studies)	m has submitted stability study data of 3 batches of Drug Substance at real time conditions for 36 months and accelerated conditions for 06 months. The real time stability data conducted at $25^0C\pm2^0C/60\pm5\%RH$.
	dule-III Drug Product:	m has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	alytical method validation/verification of product	m has submitted validation of Analytical methods of Anti- factor IIa Activity, Anti-factor Xa activity, Benzyl Alcohol determination & Sterility test. m has submitted verification of Analytical methods of Related substances & Bacterial Endotoxin test.
	ntainer closure system of the drug product	Type I Colorless Glass vial, Grey Halogenated Butyl Rubber stopper, Aluminum & Plastic combined caps.
	bility study data of drug product	m has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 40±2°C/75%RH±5% for 6 months. The real time stability study data is conducted at 25±2°C/60%±5RH for 36 months.

	marks of Evaluator	n- clinical and Clinical trial data are not submitted by the firm. Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product, hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.

evious Decision: Keeping in view the availability of product in country of origin as per submitted CoPP and Heparin Injection being non-rDNA pharmacopoeial product; Registration Board approved the product as per current Import Policy for finished drugs (M-320).

aluation by BE&R: Initially, the applied product was considered and approved in 320th meeting of Registration Board. After that, the panel comprising of Mr. Muhammad Kashif and Mr. Faisal Shehzad conducted virtual GMP inspection on 10-04-2023 & 11-04-2023 and concluded as following:

"*Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, and considering the fact that Heparin sodium is a polysaccharide (no killed/attenuated organism in final product), the panel has concluded that the firm has adequate systems to manufacture heparin sodium and appeared to comply with the cGMP requirements.* ***However, the panel also observed during virtual inspection documentary review that the manufacturer does not hold CoPP for applied strength of 25000 IU in China. Hence, the panel recommended that the provisions under DRAP Act, 2012 and relevant rules must be checked for grant of registration for such biological drugs.*** *The importing firm may also be directed to update DRAP for inclusion of manufacturing of any other biological drug in bulk production and / or filling area by the manufacturer along with their NRA approval, QRM report and re- validation of cleaning, if added in future.*"

ring further processing of the case, it was observed that the product is not licensed to be placed on the market for use in China. Recently, the firm has submitted that our product is manufactured under license of Ministry of Health of China. The product is also being exported and registered with health authorities of Republic of the Philippines, Uzbekistan and Bolivia. Copies of registration certificates for these countries have been provided.

cision of 332nd DRB Meeting:

"*Registration Board deferred the case for evidence of availability of product in the country of origin or in RRA or in any three eastern European countries from same manufacturer.****"***

marks:

ii. The firm has submitted GMP Certificate duly legalized from China Council for the Promotion of International Trade China Chamber of International Commerce.

iii. The firm has also submitted document regarding "Explanation of Pharmaceutical GMP Compliance Inspection Conclusion in Hebei Province People's Republic of China" wherein the Inspector namely "M/s Hebei Province Pharmaceutical Professional Inspector Corps (South District) conducted a pharmaceutical GMP and submitted following response:

"*The inspection conclusion is that the enterprise's F3 production line is in compliance with the requirements of the "Good Manufacturing Practice of Medical Products" of the People's Republic of China. Please refer to Pharmaceutical GMP Compliance Inspection Conclusion in Hebei Province People's Republic of China issued on 4th April 2023.***"**

cision: Registration Board deferred the case for evidence of availability of product in the country of origin or in RRA or in any three eastern European countries from same manufacturer."

Imported Human Biological on priority from non-reference countries.

Molecule: Heparin Sodium

Evaluator: Mr. Muhammad Kashif

42.	**Name, address of Applicant / Importer**	**M/s Cure Life Pharma (Private) Limited** Address: House No-283-B, Block ,Johar Town Lahore, Ground Floor.(Near Kips School).

	Details of Drug Sale License of importer	M/s Cure Life Pharma (Private) Limited, House No-283-B, Block ,Johar Town Lahore,Ground Floor.(Near Kips School).
	Name and address of marketing authorization holder (abroad)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name, address of manufacturer(s)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name of exporting country	INDIA
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Free Sale & GMP: The applicant has attached legalized copy of free sale certificate No. 105946/TS/2023 valid until 13-02-24 and legalized GMP certificate No. 98352/TS/2022 valid till 17-10-2023 issued by the Drug Control Administration of Govt. of Telangana, India
	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement from the marketing authorizer abroad hereby authorizes M/s Curelife Pharma (Private) Limited to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	y. No.889 and date 12-10-2023
	Details of fee submitted	Rs. 150,000/- Dated 03/10/2023 Fee Challan Number 388344972
	The proposed proprietary name / brand name	Stanhep-5
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Heparin Sodium…….1000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Heparin Sodium injection comes under the category of anticoagulant which is indicated for both the prevention and treatment of thrombotic

		events such as deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as atrial fibrillation (AF). Heparin is also used to prevent excess coagulation during procedures such as cardiac surgery, extracorporeal circulation, or dialysis, including continuous renal replacement therapy.
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's x 5mL vial
	Proposed unit price	Retail price as per SRO
	Shelf Life	24 months
	Storage Conditions	Store below 30 ^{O}C
	The status in reference regulatory authorities	Heparin Sodium Solution for injection 1000IU/ml is Registered in the country of the origin Spain. rug Name: HEPARIN SODIUM, API: HEPARIN SODIUM, Strength: 10,000 IU/ml. Dosage Form: INJECTABLE;INJECTION, Company Name: FRESENIUS KABI USAHeparin Injection 5000 IU/5ml of M/s Leo, Heparin Sodium Injection, USFDA approved.
	For generic drugs (me-too status)	Heparin Injection 5000 IU/5ml of M/s Leo/Zam Zam Pharma
	Module-II (Quality Overall Summary)	The applicant has submitted the Quality Overall Summary in accordance with WHO. The information has been summarized related to nomenclature, structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, impurities, specifications analytical procedures, batch analysis and justification of specifications, reference standard, container closure system stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	**/s Gland Chemicals Pvt Limited.** anufacturing Address: Fact.No,30A, IInd Phase, KIADB Industrial Area, Malur-563160, Kolar Dist, Karnataka INDIA
	Module-III Drug Substance:	The applicant has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specifications, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The applicant has submitted stability data of 3 batches at long term conditions at 25^{O}C $\pm$ 2^{O}C / 60% RH $\pm$5% for 12 months. The accelerated stability data is conducted at 40^{O}C $\pm$ 2^{O}C / 75% RH $\pm$5% for 06 months.
	Module-III Drug Product:	The applicant has submitted the data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference

		standard or materials, container closure system and stability.
	Analytical method validation/verification of product	The applicant has submitted the details of analytical method validation.
	Container closure system of the drug product	Standard pack size of Heparin Sodium is 500 MU. Heparin Sodium is packed in the Low-density polythene bag. The sealing is done thermally by a machine. The sealed bag is kept in HDPE drums
	Stability study data of drug product, shelf life and storage conditions	The applicant has submitted study data of 3 batches of heparin injection at accelerated and real time conditions. The real time stability data is conducted at $30^{O}C \pm 2^{O}C$ / 65% RH $\pm$5% for 24 months and accelerated stability data is conducted at $40^{O}C \pm 2^{O}C$ / 75% RH $\pm$5% for 06 months
	Remarks	Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.
Decision: Keeping in view valid Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized GMP Certificate, FSC / CoPP before issuance of Registration Letter.		
43.	**Name, address of Applicant / Importer**	**M/s Cure Life Pharma (Private) Limited** **Address:** House No-283-B, Block ,Johar Town Lahore,Ground Floor.(Near Kips School)
	Details of Drug Sale License of importer	M/s Cure Life Pharma (Private) Limited, House No-283-B, Block ,Johar Town Lahore,Ground Floor.(Near Kips School)
	Name and address of marketing authorization holder (abroad)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name, address of manufacturer(s)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name of exporting country	INDIA
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Free Sale & GMP: The applicant has attached legalized copy of free sale certificate No. 105946/TS/2023 valid until 13-02-24 and legalized GMP certificate No. 98352/TS/2022 valid till **17-10-2023** issued by the Drug Control Administration of Govt. of Telangana, India

	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement from the marketing authorizer abroad hereby authorizes M/s Curelife Pharma (Private) Limited to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	y. No.890 and date 12-10-2023
	Details of fee submitted	Rs. 150,000/- Dated 03/10/2023 Fee Challan Number 9257019722
	The proposed proprietary name / brand name	Stanhep-25
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Heparin Sodium……..5000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Heparin Sodium injection comes under the category of anticoagulant which is indicated for both the prevention and treatment of thrombotic events such as deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as atrial fibrillation (AF). Heparin is also used to prevent excess coagulation during procedures such as cardiac surgery, extracorporeal circulation, or dialysis, including continuous renal replacement therapy.
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1’s x 5ml vial
	Proposed unit price	Retail price as per SRO
	Shelf Life	24 months

	Storage Conditions	Store below 30 ^{O}C
	The status in reference regulatory authorities	eparin Sodium Injection, USFDA approved.
	For generic drugs (me-too status)	Heparin-Indar, 5000IU/ml, Reg. No. 107981, Heparin Injection 25000 IU/5ml of M/s Leo/Zam Zam Pharma
	Module-II (Quality Overall Summary)	The applicant has submitted the Quality Overall Summary in accordance with WHO. The information has been summarized related to nomenclature, structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, impurities, specifications analytical procedures, batch analysis and justification of specifications, reference standard, container closure system stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	**/s Gland Chemicals Pvt Limited.** anufacturing Address: Fact.No,30A, IInd Phase, KIADB Industrial Area, Malur-563160, Kolar Dist, Karnataka INDIA
	Module-III Drug Substance:	The applicant has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specifications, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The applicant has submitted stability data of 3 batches at long term conditions at 25^{O}C $\pm$ 2^{O}C / 60% RH $\pm$5% for 12 months. The accelerated stability data is conducted at 40^{O}C $\pm$ 2^{O}C / 75% RH $\pm$5% for 06 months.
	Module-III Drug Product:	The applicant has submitted the data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	The applicant has submitted the details of analytical method validation.
	Container closure system of the drug product	Standard pack size of Heparin Sodium is 500 MU. Heparin Sodium is packed in the Low-density polythene bag. The sealing is done thermally by a machine. The sealed bag is kept in HDPE drums
	Stability study data of drug product, shelf life and storage conditions	The applicant has submitted study data of 3 batches of heparin injection at accelerated and real time conditions. The real time stability data is conducted at 30^{O}C $\pm$ 2^{O}C / 65% RH $\pm$5% for 24 months and accelerated stability data is conducted at 40^{O}C $\pm$ 2^{O}C / 75% RH $\pm$5% for 06 months

	Remarks	Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.
Decision: Keeping in view valid Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized GMP Certificate /FSC / CoPP before issuance of Registration Letter.		

Molecule: FMD (Vet)
Evaluator: Mr. Muhammad Kashif

Priority /Out of que Consideration on the basis of MOU signed between Sindh Govt. and manufacturer Dollvet.Turkey and Copy of Letter From Sindh Institute of Animal Health Live stock and Fisheries Department Govt. of Sindh Adressing CEO DRAP requesting on priority approval of the FMD Vaccine to M/s Orion .Group

44.	**Name of Importer**	M/s Orion Group address P-79, Usman Block, Muslim Town No. 1, Near Lasani Pully, Sargodha Road, Faisalabad
	DSL details	M/s Orion Group address 79 Commercial Area , Usman Block, Muslim Town No. 01, Sargodha Road, Faisalabad DSL 06-331-0167-022405D,valid till . 20 –November 2023
	Name of Manufacturer	Product License Holder & Manufacturer M/s DOLLVET Biyotechnology A.S. Konaklar Mah. Akasyali Sok. No.10, Besiktas/ Istambul, Turkey Production Site:Kocoren OSB Mahallesi 106.Cadde No:6 Eyyubiya/Sanliurfa
	Brand Name + Dosage Form + Strength	AFTODOLL-JEL Suspension for Injection Inactivated viral vaccine
	Composition	Each dose of vaccine (2 ml) are as follows: **Active Ingredients**** O (PanaAsia-2)) ……..…… ≥ 6 PD50* A (Iran-05) ……..... ≥ 6 PD50* ASIA-1 (Sindh-08)……. ≥ 6 PD50* * PD50 – 50% bovine protective dose according to European Pharmacopoeia 0063 The number and type of vaccine strains included in the final product will be determined according to the epidemiological situation of the country/region and indicated on the label **Excipients** Aluminum hydroxide (Al+3)……. … 1.0 mg/ml Saponin…… 1.5 mg/ml
	Finished product specifications	Ph.Eur Specifications
	Pharmacological Group	Biological Inactivated Viral Veterinary vaccine
	Shelf life	18 months 2-8 ^{O}C
	International availability	Not Submitted
	Products already registered in Pakistan	oot and mouth Disease Vaccine manufactured by FGBI Arriah Russia, Reg. No.052400, importer Mustafa Brothers
	Type of Form, Dy. No. Date of Application, Fee submitted	Form5-ADy. No.413 Date:23-01-2024 Fee Submitted: Rs150,000, Dated: 28-01-2024

	Demanded Price / Pack size	Decontrolled for Veterinary products/ 50ml bottle
	General Documentation	• Original Legalized CoPP valid till 25-11-2025 which also specifies the free sale of the product in countryof origin, GMP certificate and Product Agent Agreement and Power of Attorney are submitted • Copy of MOU Between Sindh Govt. and manufacturer Dollvet.Turkey • Copy of Letter From Sindh Institute of Animal Health Live stock and Fisheries Department Govt. of Sindh Adressing CEO DRAP requesting on priority .approval of .the FMD Vaccine to M/s Orion Group
	Remarks of BE&R	Additional fee of Rs.1,50,000/- is required to be submitted.
Decision: The Board deliberated on the letter of SIAH, Sindh stating that product shall be imported in Bulk and diluted in the premises of SIAH. Keeping in view the Board deferred the case for clarification whether the product will imported in finished form or as bulk import and local repack.		

Item No. IV. Division of Quality Assurance & Laboratory Testing

S. No.	Case title
01	CANCELLATION/SUSPENSION OF REGISTRATION OF WATER FOR INJECTION 2ml (REGISTRATION NO. Q24873) MANUFACTURED BY M/S AMSON VACCINES PHARMA (PVT) LTD, PLOT #154, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.
02	MANUFACTURE & SALE OF SUB-STANDARD BLOMOX FORTE SUSPENSION, REG. NO. 026072, BATCH NO. PF-045, MANUFACTURED BY M/S. BLOOM PHARMACEUTICALS (PVT) LTD., HATTAR.
03	MANUFACTURE & SALE OF SUB-STANDARD KEMODRYL COUGH SYRUP BATCH NO. K-1068 MANUFACTURED BY M/S ALKEMY PARMACEUTICAL LABORATORIES (PVT) LTD., HYDERABAD.

Case No. 01: CANCELLATION/SUSPENSION OF REGISTRATION OF WATER FOR INJECTION 2ml (REGISTRATION NO. Q24873) MANUFACTURED BY M/S AMSON VACCINES PHARMA (PVT) LTD, PLOT #154, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.

FID-I Islamabad along-with Assistant Director QA-I, inspected the premises of M/s Amson Vaccines & Pharma (Pvt)Ltd 113 Industrial Triangle Kahuta Road Islamabad on 16th June 2022 to review the GMP compliance of the firm. During the course of inspection, the panel came to know that the firm is carrying out manufacturing of the subject mentioned product whereas they do not have approved section for manufacturing of the said item i.e. Liquid Injectable Vial-SVP (general) from the CLB. Chairman CLB vide letter no. F.l-26/94-Lic(PtVol-I) dated 30th June allowed renewal of tablet section (General), Capsule section (General), Oral Liquid section (General), Liquid Ampoule injection (vaccine), Liquid vial injection (Vaccine / Sera) Dry powder injection (Steroid), Quality control Laboratory and warehouse.

02. FID I reported that the firm is currently manufacturing their Water for Injection in the Vaccine facility. Moreover, the filling of WFI is being done on the same filling machine as their other vaccines without undertaking Cleaning validation as for all of these vaccines limit of detectability is not available.

03. The firm is utilizing their water for Injection only for inclusion as reconstitution medium in their product Inj. Hyzonate (powder for reconstitution) whereas the Registration letter of Inj. Hyzonate does not specifically mention that only WFI manufactured by M/s Amson Vaccines & Pharma has to be included.

04. After the subject mentioned inspection, the firm submitted letter No. F. l-26/94-Lic(Pt-l) dated 14th December 2021 regarding Approval of layout plan for regularization/revised/new sections under DML No. 000393 (Formulation) issued by the Licensing wherein approval for Tablet (Psychotropic), Liquid injectable Vial-SVP, Dry powder for injection (Steroid), Quality control lab and Warehouse. Additionally, the firm submitted an undertaking that they will finish construction of Liquid Injectable Vial-SVP (general) within one year which clearly indicates without a doubt that as of right now the firm does not have approved section for manufacturing of Water for injection 2ml registration No.024873.

05. FID I reported that the panel advised the firm that they should get Approval of Liquid Injectable Vial-SVP (general) for manufacturing of Water for Injection in the existing facility in the interim period till construction/completion of the new building, the feasibility of which had been pointed/laid out to the firm in the closing meeting of the inspection. The firm however, point blank refused to consider the possibility even though it was made clear to the firm that they are undertaking an illegal activity. Furthermore, the firm was verbally directed to immediately stop production until the approval of Liquid Injectable Vial-SVP (general) from CLB, the firm however, adamantly and willfully refused to comply with the instructions and insisted on illegal manufacturing whereby, the firm stands in obstruction of Power of the Inspector granted under Section 18(l)(j) & punishable under Section 27(3) of Drugs Act,1976 read with Schedule-Ill (3) of DRAP Act, 2012

06. Keeping in view the above-mentioned facts of the case, FID I has recommended following actions against M/s. Amsons Vaccine and Pharma Islamabad:

i. Cancellation/Suspension of Registration of Water for injection 2ml registration No.024873 until the firm either completes the new building or gets section approval from CLB in the existing facility since as of today the firm M/s Amson Vaccines & Pharma (Pvt) l td do not have the requisite section approval from CLB
ii. Permission for prosecution against M/s Amson Vaccines & Pharma (Pvt) Ltd plot# 154 Industrial TriabngleKahuta Road, Islamabad through its management Mr. Abbas Khan S/O Dilawar Khan, Mr. Shamim Ahmad S/O Abdul Majeed. Mr. Saleem Asghar S/O Ali Sagheer, its Plant Manager Mr. Amanullah Sial, its Production In-charge Mr. Sajjad Hussain S/O M. Bashir & bits QC Incharge Mr. MuammadMuddassir S/O Noor Muhammad under Section 27(3) of Drugs Act, 1976 read with Schedule-Ill (3) of DRAP Act, 2012.

07. Proceedings and Decision of 320th meeting, “The case has been deferred due to paucity of time”.

08. Decision of 321st meeting Keeping in view position narrated above. Board decided: “To issue show cause notice to M/s. Amson Vaccines & Pharma (Pvt) Ltd, Islamabad for suspension/cancellation/ prosecution in Drug Court, Islamabad for manufacturing of Water for injection 2ml registration No.024873 in vaccine manufacturing facility and called them for personal hearing before Registration Board as per clause 5.2 of Schedule B under Drugs (L, R & A) Rules, 1976.& Advised to proceed as per Section 27 (3) of Drugs Act, 1976 regarding obstruction in official duties as it does not pertain to Registration Board.”

09. In compliance to the decision of RB show cause was issued to firm vide letter No. 03-45/2022 QC dated 15-11-22 to which M/s. Amsons Vaccine and Pharma Islamabad vide letter AVP/1222/WFI02 dated 23-12-2022 & letter AVP/1222/WFI01 dated 13-12-2022 has briefed that their layout for aseptic filling activity for WFI in vacant room in this sterile section has been approved and they need 4-6 months for its operation and till then aseptic filling of WFI 2ml after appropriate decontamination, cleaning, and on basis of cleaning validations may please be allowed in existing area.

10. Proceedings and Decision of 324th Meeting of Registration Board.
Registration Board after discussion, considering the facts of the case decided:

i. "Suspension of Registration of "Water for injection 2ml registration No.024873" of M/S Amson Vaccines Pharma till establishment and approval of separate section by Licensing Division, DRAP for manufacturing of this product with immediate effect."

11. In compliance to the above mentioned decision, letter vide F. No. 3-04/2023-QC (324-RB) dated 14-03-2023 was issued to M/s. Amson Vaccines & Pharma Islamabad.

12. M/s. Amson Vaccines and Pharma (Pvt.) Ltd., Islamabad vide letter Ref# RF-1223-178 informed the division of QA&LT that the Central Licensing Board in its 293rd meeting held on 14-12-2023 granted "Water for injection section (Revised)" to their firm and has requested the Registration Board to allow them to resume the production of their product namely "Water for injection, Reg. No. 024873". Along with their request, the firm has further attached letter for grant of section issued by the Secretary CLB (F. No. 1-26/94-Lic(Vol-II) dated 14-12-2023), request for constitution of panel for inspection by the division of Drugs Licensing (Ref# RA-0823-112 dated 16-08-2023), letter of constitution of panel by the division of Drugs Licensing (No. F. 1-26/94-Lic(Vol-II) dated 18-10-2023) and Inspection report submitted by panel wherein the panel has recommended as under:

"Keeping in view the above facts on record and the people met, documents reviewed during the vision, the panel unanimously ***recommended the grant/relocation of Following additional section*** *to M/s Amson Vaccines & Pharma (Pvt) Ltd. Plot# 154 Industrial Triangle, Kahuta Road Islamabad.*

i. ***Water for injection Section"***

Request of the firm M/s. Amson Vaccines and Pharma (Pvt.) Ltd., Islamabad vide letter Ref# RF-1223-178 to resume production of "Water for injection 2ml, Registration No.024873" is Submitted for consideration of the Board.

Proceedings and Decision of 334th Meeting of Registration Board:

The Board was appraised regarding the decision of 293rd meeting of Central Licensing Board, where in the CLB granted approval of Water for Injection Section was granted to M/s. Amson Vaccines and Pharma (Pvt.) Ltd., Islamabad. Keeping in view grant of Section by the CLB, Registration Board acceded to request of firm for resumption of production of their product namely, Water for injection, Reg. No. 024873.

Case No. 02: **MANUFACTURE & SALE OF SUB-STANDARD BLOMOX FORTE SUSPENSION, REG. NO. 026072, BATCH NO. PF-045, MANUFACTURED BY M/S. BLOOM PHARMACEUTICALS (PVT) LTD., HATTAR.**

Details of sample:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Remarks of CDL
Blomox Forte Suspension	Bloom Pharmaceutical (Pvt.) Ltd. Hattar	026072	PF-045	03-2021	02-2023	Substandard on the basis of Deliverable volume.

Details of CDL report:

S.No.	Test	Acceptance Criteria	Result	Reference

1.	Description	Off white which reconstitute into off white suspension on mixing with water.	Complies.	Mfg. Specs.
2.	Identification	The identification test must identify Amoxicillin.	Complies.	USP 43
3.	**Deliverable Volume**	**Meets the requirement of general chapter <698>**	**Does not comply.**	**USP 43**
3.	pH	5.0 to 7.5	5.79-Complies	USP 43
4.	**Assay** Amoxicillin (Label Claim 250mg/5ml)	90.0% to 120.0%	113.74%- Complies.	USP 43

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

Summary of the case:

ii. Federal Inspector of Drugs-IV, DRAP Islamabad was taken the sample of Blomox forte suspension manufactured by Ms. Bloom Pharmaceuticals Pvt. Ltd., Hattar from the premises of M/s. Federal Government Polyclinic Hospital, Islamabad on 06-08-2021.

iii. FID also ordered not to dispose of the stock (3565 bottles) of Blomox forte suspension subject to report of test and analysis of the product for volume and content uniformity under clause (i) of section 18 of the Drug Act 1976.

iv. The sample of drugs sent to Government Analyst, CDL for test and analysis on form-4 dated 09-08-2021. Federal Govt. Analyst CDL Karachi vide report No.R.IP.66/2021 dated 22-09-2021 has declared the sample as "Sub-standard" quality under the Drugs Act, 1976.

v. FID directed firm to stop the sale and recall the said drug and explain their position.

vi. Recall of product was initiated and reconciled by FID, it was revealed that batch size of product was 9300 packs and actual yield was 9010 packs+100 packs utilized by QC department. Ms. Bloom Pharma issued stock of 9000 bottles to its distributor Ms. Chaudhary Pharma, Rawalpindi which they issued to Ms. Biocare Enterprises and they supplied 9000 bottles to Polyclinic Hospital, Islamabad.

vii. M/s. Bloom Pharmaceutical Pvt. Ltd., Hattar replied to FID dated 21-10-2021 wherein they requested for retesting on the ground that **"as per in-house testing performed by the Quality Control Department, the product comply all test specifications. Their Quality Control Department released the product for market after thorough tests and all specifications of the product were within limits and found no contravention of Drug Act, 1976."**

viii. Firm has been directed to submit scientific justification/evidence for retesting dated 25-11-2021.

ix. Firm replied dated 31-10-2021 where in their results of finished product and retained sample were as per specification. Firm has performed test on 10 containers which are in specification as per their documents

x. As per decision of 313th meeting of Registration Board regarding appellate testing, CDL was asked for OOS investigation.

xi. Federal Government Analyst, CDL Karachi submitted that

> ***"The sample in question was tested for Deliverable volume along with other quality test as per USP General Chapter<698> and as desired by the FID. The sample was declared as of substandard quality on the basis of the test performed. It is submitted that the test of deliverable volume requires thirty (30) containers and the quantity submitted to CDL, Karachi by the FID vide memorandum No. F.7-2/2011-FID-I (Vol-I) dated 09-08-2021, was only fifty (50) containers, therefore, No Systematic Out of Specification Investigation could be made for this sample."***

Proceedings and Decision of 324th meeting of Registration Board:

"The Registration Board deferred the case for further deliberation along with confirmation of Dry Powder Suspension (penicillin)"
In view of Board's decision, the matter has been forwarded to Licensing Division for confirmation of section of Dry Powder Suspension Penicillin. Licensing Division has informed that **"As per the available record of this Division, the firm does not possess the formal approval of the Dry powder suspension (penicillin) section."**

Proceedings and Decision of 334th Meeting of Registration Board:

"The Board was appraised regarding manufacturing of Penicillin products without having approved Penicillin Section. The Board after deliberation decided to issue show cause notice to M/s. Bloom Pharmaceutical Pvt. Ltd., Hattar for suspension / cancellation of product Blomox Forte Suspension Reg. No. 026072 and all other registered penicillin products without having approved section, which is violation of clause 5.2 of Schedule B under Drugs (L, R & A) Rules, 1976 and called them for personal hearing before Registration Board in its forthcoming meeting."

CASE NO. 03: MANUFACTURE & SALE OF SUB-STANDARD KEMODRYL COUGH SYRUP BATCH NO. K-1068 MANUFACTURED BY M/S ALKEMY PARMACEUTICAL LABORATORIES (PVT) LTD., HYDERABAD.

The Federal Inspector of Drug, DRAP, Peshawar inspected M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd., Hyderabad wherein following sample along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Remarks
Kemodryl Cough Syrup	Ms. Alkemy Parmaceutical Laboratories (Pvt) Ltd., Hyderabad.	007069	K-1068	Aug 2023	July 2025	Sub-Standard on assay.

02. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Sub-Standard" quality vide their test report No. KQ-8-23-000108 dated 09th October 2023. Results of CDL on the basis of which sample under reference has been declared as Sub-Standard quality are reproduced as under: -

S. No.	Test	Acceptance criteria	Result	Reference
1	Description	A dark red coloured expectorant with menthol smell.	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Chlorpheniramine maleate, Sodium citrate and Ammonium chloride. Paracetamol	Complies	Mfg. Specs.
3	**Assay** Chlorpheniramine maleate (Labe claim 4mg/ 5ml)	85.0% to 115.0%	97.3% complies.	Mfg. Specs.
4	**Assay** Sodium citrate (Label claim 55mg/ 5ml)	85.0% to 115.0%	**242.4%-Does not comply.**	

5	**Assay** Ammonium chloride (Label claim 125mg/ 5ml)	85.0% to 115.0%	95.0% Complies	

Remarks:- 1) The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.

03. Recall to manufacturer had been issued dated 26-10-2023.

04. FID, DRAP, Peshawar informed that the firm has requested for retesting.

05. As per decision of 313th meeting of Registration Board regarding appellate testing, Firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation.

06. M/s. Alkemy Pharmaceutical Laboratories Pvt Limited, Hyderabad submitted OOS investigation report as satisfactory along with test reports.

07. FGA, CDL submitted OOS investigation with the remarks: "The sample does not comply with respect to assay testing." The assay of Sodium Citrate was found 242.4%.

08. Firm submitted recall log, Area FID has been requested for verification of recalled stock, reply awaited.

Technical Evaluation of OOS Investigation:

i. The product was declared as sub-standard on the basis of assay of Sodium citrate (242.4%)
ii. There may be issues during manufacturing processes.
iii. Firm submitted that their OOS investigation is satisfactory and assay limit of Sodium citrate is 96.96%.
iv. While OOS investigation received from FGA, CDL, Karachi shows that assay of Sodium Citrate is 242.4%.

Proceedings and Decision of 334th Meeting of Registration Board:

- **QALT Division appraised about the history of firm regarding manufacturing of substandard liquid syrups. QALT Division also presented Out of Specification (OOS) investigations and testing records submitted by M/s. Alkemy Pharmaceutical Laboratories Pvt Limited, Hyderabad and CDL, DRAP Karachi before Registration Board.**

- **After thorough discussion and deliberation on the OOS investigation report, the Board did not acceded to request of the firm for appellate testing of Kemodryl Cough Syrup , Batch No. K-1068 manufactured by M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd., Hyderabad and to issue show cause notice to M/s. Alkemy Parmaceutical Laboratories (Pvt) Ltd., Hyderabad for manufacturing and sale of Substandard Kemodryl Cough Syrup , Batch No. K-1068 and called them for personal hearing before Registration Board in its forthcoming meeting.**

Meeting ended with vote of thanks to and from Chair.

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