MINUTES OF 333rd MEETING OF REGISTRATION BOARD HELD ON 19TH & 20TH DECEMBER, 2023

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

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333rd meeting of Registration Board was held on 19th & 20th December, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad.

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

Following members attended the meeting:

1.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law & Justice, Islamabad.	Member
2.	Mr. Ghulam Mujtaba, Deputy Director, Rep. of IPO, Islamabad.	Member
3.	Dr. Imranullah Khan, Senior Drug Analyst. Rep of Director DTL, Govt. of KP	Member
4.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan Quetta	Member
5.	Mr. Iftikhar A. Chaudhary, Hospital Pharmacist, Lahore	Co-opted Member
6.	Dr. Ayesha Yaqoob, Deputy Drug Controller, Rep. of DTL, Rawalpindi	Member
7.	Ms. Mahvash Ansari, Additional Director, Rep. of QA&LT, DRAP, Islamabad.	Member
8.	Mr. Muhammad Kashif, Deputy Director, Rep. of Director, Division of BE&R	Member
9.	Ch. Zeeshan Nazir Bajar, Additional Director	Secretary
10.	Ms. Sadaf Ahmad, Assistant Director, Rep. of Director, MD&MC Division	Member
11.	Dr. Qurban Ali, Ex-Director General, NVL, Veterinary Expert	Co-opted Member

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

Item No. I. Confirmation of Minutes of 332nd meeting of Registration Board

332nd meeting of Registration Board was held on 05th December, 2023. Accordingly, draft partial minutes related to M/s Flow Pharma, Lahore (Directions of Chairman, Drug Court, Rawalpindi) of the meeting were prepared and circulated among the members through email and WhatsApp group of Registration Board on the same day for their perusal / approval / comments (if any) and response before 1500 Hrs. Mr. Muhammad Aslam, Additional Draftsman, Ministry of Law & Justice Division, Islamabad, Mr. Iftikhar A. Chaudhary, Co-opted Member, Registration Board and Mr. Adnan Rizvi through WhatsApp group agreed with the draft minutes. Rest of the members did not comment. Hence partial draft minutes stand approved. Accordingly, fair partial minutes of 332nd meeting were signed and sent to relevant Division for compliance / implementation of decision of Board.

Later on, draft partial minutes of Biological Division were circulated among the members through email on 12th December, 2023 for perusal / approval / comments (if any) and response by 16th December, 2023at 10:00 am. Mr. Adnan Rizvi, Director, DTL, Sindh and Mr. Iftikhar A. Chaudhary, Co-opted Member though WhatsApp group on 13th December agreed with draft minutes of the meeting related to Biological Division. Lt. Gen.(R) Prof. Dr. Karamat A. Karmat, through email on 16th December, 2023 agreed with minutes of 332nd meeting of Registration Board. Hence minutes of 332nd meeting of Registration Board stand approved. Accordingly, fair minutes of 332nd meeting were signed and sent to Biological Division for compliance / implementation of decision of Board.

Decision: **Registration Board noted the information and unanimously confirmed minutes of 332nd 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.	Mr. Ammar Ashraf Awan	Evaluator PEC-II	1 – 129
2.	Mr. Salateen Waseem Philip	Deputy Director (PE&R)	130 – 367
3.	Mr. Adil Saeed	Evaluator PEC-IX	268 – 320
4.	Ms. Najia Saleem	Evaluator PEC-X	321 – 407
5.	Dr. Farhadullah	Evaluator PEC-XI	408 – 416
6.	Ms. Saima Hussain	Evaluator PEC-XV	417 – 457
7.	Ms. Sana Kanwal	Evaluator PEC-XX	458 – 482
8.	Ms. Maham Misbah	Evaluator PEC-XXIII	483 – 504
9.	Mr. Shahid Nawaz	Evaluator PEC-XIII	505 – 529
10.	Mr. M. Tahir Waqas	Evaluator PEC-XXI	530 – 549
11.	Mst. Farzana Raja	Evaluator PEC-IV	550 – 572
12.	Dr. M. Haseeb Tariq	Evaluator PEC-III	573 - 664

Agenda of Evaluator PEC-II

Case no. 01 Registration applications for local manufacturing of (Human) drugs on Form 5F.

New cases

1.	**Deleted**
2.	**Deleted**
3.	**Deleted**
4.	**Deleted**

The cases sr. no. 1-4 were placed on agenda being the missed applications of the already addressed strengths of the firm under the chapter of Export facilitation. As no application of export facilitation was considered in current agenda so the board decided to delete these applications from this agenda and will be taken along with the applications of other firms under the export facilitation chapter when addressed.

5. `	**Name and address of manufacturer / Applicant**	**M/s PDH Pharmaceutical Pvt. Ltd., 19-Km, Ferozpur Road Lahore.**
	Brand Name + Dosage Form + Strength	Ferobion Drops
	Composition	Each ml Contins: Iron III Hydroxide Polymaltose Complex Eq. To Elemental Iron…50mg
	Diary No. Date of R& I & fee	Dy.No 13002 dated 06-04-2018 Rs.20,000/- dated 05-04-2018
	Pharmacological Group	Antianeamic
	Type of Form	Form-5 Duplicate dossier verified from R&I section
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Addfer Syrup 50mg/5ml of Acto Labs, Karachi
	GMP status	Panel inspection report dated 20-09-2017 recommends renewal of DML
	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter along with latest GMP inspection report conducted within last three years.	
6. `	**Name and address of manufacturer / Applicant**	**M/s PDH Pharmaceutical Pvt. Ltd., 19-Km, Ferozpur Road Lahore.**
	Brand Name + Dosage Form + Strength	Relieve 550mg Tablet
	Composition	Each Film Coated Tablet Contains: Naproxen Sodium…550mg
	Diary No. Date of R& I & fee	Dy.No 13001 dated 06-04-2018 Rs.20,000/- dated 05-04-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Health Canada approved

	Me-too status (with strength and dosage form)	Fougera Tablet of M/s Hiranis Reg # 076489
	GMP status	Panel inspection report dated 20-09-2017 recommends renewal of DML
	Remarks of the Evaluator II:	
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
7. `	**Name and address of manufacturer / Applicant**	**M/s PDH Pharmaceutical Pvt. Ltd., 19-Km, Ferozpur Road Lahore.**
	Brand Name + Dosage Form + Strength	Montana 4mg Sachet
	Composition	Each Sachet Contains: Montelukast as Sodium…4mg
	Diary No. Date of R& I & fee	Dy.No 13000 dated 06-04-2018 Rs.20,000/- dated 05-04-2018
	Pharmacological Group	Leukotriene antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Montelukast Sodium 4 mg Oral Granules by M/s Highnoon Laboratories, MHRA Approved.
	Me-too status (with strength and dosage form)	Aerotel Sachet of M/s Highnoon Laboratories. (Reg.#044768)
	GMP status	Panel inspection report dated 20-09-2017 recommends renewal of DML
	Remarks of the Evaluator II:	
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
8. `	**Name and address of manufacturer / Applicant**	**M/s PDH Pharmaceutical Pvt. Ltd., 19-Km, Ferozpur Road Lahore.**
	Brand Name + Dosage Form + Strength	Al-Zero 2.5mg/5ml Syrup
	Composition	Each 5ml Contains: Levocetirizine Dihydrochloride…2.5mg
	Diary No. Date of R& I & fee	Dy.No 12999 dated 06-04-2018 Rs.20,000/- dated 05-04-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xyzal of (USFDA approved)
	Me-too status (with strength and dosage form)	Concidol-L Syrup of M/s Convell Laboratories
	GMP status	Panel inspection report dated 20-09-2017 recommends renewal of DML
	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter along with latest GMP inspection report conducted within last three years .	

Contract manufacturing applications as per decision of 173rd meeting of Authority:

Authority in its 173rd meeting has decided as under:

"The Authority, in order to further enhance the working efficiency and quick disposal of pending registration applications, approved to create a separate queue for registration applications for contract manufacturing submitted on Form-5F in the order of date of submission. This Queue will be updated after each meeting of Registration Board."

Rule Position as per The Drugs (Licencing, Registering & Advertisement) Rules, 1976 is as under

"20A. Contract manufacture.- (l) Manufacture or analysis, through contract, either for local sale or export purpose, shall be permissible by contract giver if:-
a licenced pharmaceutical manufacturer having licence to manufacture by way of formulation: or
an importer for its already registered drug products in Pakistan for permission from finished drug product import to contract manufacturing by a licenced pharmaceuticalmanufacturer; or
a foreign pharmaceutical company (manufacturer or marketing authorization holder) having drug sale licence in Pakistan for their research, innovator, originator drug productsor drug products already registered for sale by any of reference regulatory authorities adopted by the Registration Board; or
licenced pharmaceutical manufacturing unit, which is granted a certificate by Registration Board to the effect that the unit is unable to maintain its production or output level due to reasons beyond its control, including but not limited to repair or upgradation requirements:

Provided that the contract manufacturing under this clause shall be for a period of thirty months extendable for a further period of twenty-four months by the Registration Board on valid grounds.

The Board considered the cases of contract manufacturing in the light of rule 20 A of the Drugs (Licencing, Registering & Advertisement) Rules, 1976 and discussed the application/implementation of said rules..

The member of registration board representing the Law and Justice Division, Governemnt of Pakistan opined that the sub Rule *a of the rule 20 (A)* is clear and does allow/permit to *manufacture or analysis, through contract, either for local sale or export purpose by* a licenced manufacturer from other licenced manufacturer and
all the sub rules i.e, a, b, c and d are independent clauses and does not bar each other on their applicability and
The proviso is only for the sub rule *d of the rule 20 (A)* and is not applicable to all sub rules.

Following registration applications of contract manufacturing are now presented for consideration of Registration Board

9.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial.section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 7488 dated 15-03-2023 Rs.75,000/- dated 21-12-2022

<table>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Closmat 2 MIU Dry Powder Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Colistimethate Sodium…2 MIU</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Dry Powder for injection (IM/IV)</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibacterial for systemic use, other antibacterial, polymyxins.</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>As per USP Specs.</td></tr>
<tr><td></td><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Colistimethate Sodium 2 million I.U. Powder for Solution for Injection. (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Nogotex injection of M/s Nabiqasim Industries</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td></td><td colspan="2">The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:
<table>
<tr><td>Applicant firm</td><td>M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.</td></tr>
<tr><td>Brand Name</td><td>Colizon 2 million IU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.</td></tr>
<tr><td>10.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Horizon Healthcare (Pvt.) Ltd.
Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial.section.</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>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 7490 dated 15-03-2023 Rs.75,000/- dated 21-12-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Closmat 4.5 MIU Dry Powder Injection</td></tr>
</table>

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium…4.5 MIU
	Pharmaceutical form of applied drug	Dry Powder for injection (IM/IV)
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial, polymyxins.
	Reference to Finished product specifications	As per USP Specs.
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Coly-Mycin-M Parenteral 4.5 million IU by Searchlight Pharma Inc of (Health canada Approved)
	For generic drugs (me-too status)	Kolisod injection of M/s Bristol Mayer Biotech
	Name and address of API manufacturer.	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Manufacturer firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Brand Name: Colizon 4.5million IU Injection	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
11.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial.section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 7489 dated 15-03-2023 Rs.75,000/- dated 21-12-2022
	The proposed proprietary name / brand name	**Closmat 3 MIU Dry Powder Injection**
	Strength / concentration of drug of Active	Each Vial Contains:

	Pharmaceutical ingredient (API) per unit	Colistimethate Sodium…3 MIU
	Pharmaceutical form of applied drug	Dry Powder for injection (IM/IV)
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial, polymyxins.
	Reference to Finished product specifications	As per USP Specs.
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Colistimethate Sodium 3 million I.U. Powder for Solution for Injection. (MHRA Approved)
	For generic drugs (me-too status)	Nogotex injection 3MIU of M/s Nabiqasim Industries Reg# 110207
	Name and address of API manufacturer.	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Manufacturer firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Brand Name: Colizon 3 million IU Injection	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
12.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial.section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 852 dated 10-01-2023 Rs.75,000/- dated 20-12-2022
	The proposed proprietary name / brand name	**Posa 100mg Tablet**
	Strength / concentration of drug of Active	Each Film Coated Delayed Release Tablet

	Pharmaceutical ingredient (API) per unit	Contains: Posaconazole…100mg
	Pharmaceutical form of applied drug	Film coated delayed release Tablet
	Pharmacotherapeutic Group of (API)	J02AC04, Antimycotics for systemic use, Triazole and tetrazole derivatives.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	NOXAFIL (posaconazole) 100mg delayed-release tablets of MERCK SHARP DOHME, (USFDA Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Bright Gene Pharmaceutical Co., Ltd. No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
13.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt. Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 853 dated 10-01-2023 Rs.75,000/- dated 20-12-2022
	The proposed proprietary name / brand name	**Posa 200mg/5ml Oral Suspension**

Applicant firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
Manufacturer firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
Brand Name	**POZULEN 100mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Suspension Contains: Posaconazole…200mg
	Pharmaceutical form of applied drug	Oral Suspension
	Pharmacotherapeutic Group of (API)	J02AC04, Antimycotics for systemic use, Triazole and tetrazole derivatives.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	NOXAFIL (posaconazole) Oral Suspension of SCHERING, (USFDA Approved).
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Bright Gene Pharmaceutical Co., Ltd. No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, China.

Evaluation by PEC:

The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
Manufacturer firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
Brand Name	**Pozulen Oral Suspension 200mg/5ml**

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

14.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 2558 dated 26-01-2023 Rs.75,000/- dated 30-11-2022
	The proposed proprietary name / brand name	**Linz 72mcg Capsule**
	Strength / concentration of drug of Active	Each Capsule Contains:

	Pharmaceutical ingredient (API) per unit	Linaclotide Pellets Eq. to Linaclotide…72mcg
	Pharmaceutical form of applied drug	White to off white colored pellets filled in hard gelatin capsule size '3'
	Pharmacotherapeutic Group of (API)	A guanylate cyclase-C agonist, used to treat different types of constipation.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	LINZESS capsules 72mcg approved by (US-FDA)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Apogen Remedies Private Limited. Plot No. 55/A; Survey # 321; Biotech Park; Phase-III; (TSIIC); Karkapatla Village; Markook Mandal; Siddipet District; Telangana; 502281; India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Manufacturer firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Brand Name: **Cluzee 72mcg Capsule**	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
15.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 2559 dated 26-01-2023 Rs.75,000/- dated 30-11-2022
	The proposed proprietary name / brand name	**Linz 145mcg Capsule**
	Strength / concentration of drug of Active	Each Capsule Contains:

	Pharmaceutical ingredient (API) per unit	Linaclotide Pellets Eq. to Linaclotide…145mcg
	Pharmaceutical form of applied drug	White to off white colored pellets filled in hard gelatin capsule size '3'
	Pharmacotherapeutic Group of (API)	A guanylate cyclase-C agonist, used to treat different types of constipation.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	LINZESS capsules 145mcg approved by (US-FDA)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Apogen Remedies Private Limited. Plot No. 55/A; Survey # 321; Biotech Park; Phase-III; (TSIIC); Karkapatla Village; Markook Mandal; Siddipet District; Telangana; 502281; India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Manufacturer firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Brand Name: **Cluzee 145mcg Capsule**	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
16.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 2560 dated 26-01-2023 Rs.75,000/- dated 30-11-2022
	The proposed proprietary name / brand name	**Linz 290mcg Capsule**
	Strength / concentration of drug of Active	Each Capsule Contains:

	Pharmaceutical ingredient (API) per unit	Linaclotide Pellets Eq. to Linaclotide…290mcg
	Pharmaceutical form of applied drug	White to off white colored pellets filled in hard gelatin capsule size '3'
	Pharmacotherapeutic Group of (API)	A guanylate cyclase-C agonist, used to treat different types of constipation.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	LINZESS capsules 290mcg approved by (US-FDA)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Apogen Remedies Private Limited. Plot No. 55/A; Survey # 321; Biotech Park; Phase-III; (TSIIC); Karkapatla Village; Markook Mandal; Siddipet District; Telangana; 502281; India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. have already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Manufacturer firm: M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan. Brand Name: **Cluzee 290mcg Capsule**	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
17.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 1377 dated 16-01-2023 Rs.75,000/- dated 20-12-2022
	The proposed proprietary name / brand name	**Azilsa-C 40/25 mg Tablet**
	Strength / concentration of drug of Active	Èach Tablet Contains:

	Pharmaceutical ingredient (API) per unit	Azilsartan Medoxomil as Potassium…40mg Chlorthalidone…25mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Azilsartan Medoxomil Potassium: Angiotensin II antagonist Chlorthalidone: Benzothiadiazine Diuretic
	Reference to Finished product specifications	As per innovator
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	EDARBYCLOR Tablet approved by US-FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**Azilsartan Medoxomil Potassium:** CTX Life Sciences Pvt Ltd Block no: 251-252-Sachin-Magdalla Road GIDC Sachin, Surat-394 230 Gujrat India **Chlorthalidone**: Menadiaona S.L Poligon Industrial Mas Puigvert s/n,08389 Palafolls, Barcelona, Spain
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
Manufacturer firm	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
Brand Name	Azila-C Tablet 40/25

	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
18.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
	GMP status of the manufacturer	cGMP certificate on the basis of evaluation conducted on dated 16.08.2022 and valid till 15-08-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 17-08-2022 specifying Dry Powder injection vial section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission & Details of fee submitted	Dy.No 4039 dated 13-02-2023 Rs.75,000/- dated 20-12-2022
	The proposed proprietary name / brand name	**Azilsa-C 40/12.5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Èach Tablet Contains: Azilsartan Medoxomil as Potassium…40mg Chlorthalidone…12.5mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Azilsartan Medoxomil Potassium: Angiotensin II antagonist Chlorthalidone: Benzothiadiazine Diuretic
	Reference to Finished product specifications	As per innovator
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	EDARBYCLOR Tablet 40mg/12.5mg approved by US-FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**Azilsartan Medoxomil Potassium:** CTX Life Sciences Pvt Ltd Block no: 251-252-Sachin-Magdalla Road GIDC Sachin, Surat-394 230 Gujrat India **Chlorthalidone**: Menadiaona S.L Poligon Industrial Mas Puigvert s/n,08389 Palafolls, Barcelona, Spain
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt.) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 326th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Azila-C Tablet 40/12.5	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
19.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharmevo Private Limited.** **Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan
	GMP status of the manufacturer	GMP inspection conducted on 07th October 2021
	Evidence of approval of manufacturing facility	New section granted on 24/11/2021 Injectable Ampoule BF (steroid) -

	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 7912 dated 20-03-2023 Rs.75,000/- dated 01-03-2023
	The proposed proprietary name / brand name	**Bunide 1mg/2ml Inhalation**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2 ml Respule contains: Budesonide…….1mg
	Pharmaceutical form of applied drug	Suspension for inhalation
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	BP specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Pulmicort Inhalation Suspension 1mg/2ml (Manufacturer: AstraZeneca)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Industriale Chimica S.R.L Via E.H Grieg,13-21047 SARONNO (VA)
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Hudson Pharma Private Limited Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm	M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan
	Manufacturer firm	M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan
	Brand Name	Actonide Suspension for Nebulisation 1mg/2ml
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
20.	Name, address of Applicant / Marketing Authorization Holder	**M/s Swiss Pharmaceuticals Pvt Ltd.** **A-159, S.I.T.E Super Highway, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.

	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 197 dated 03-01-2023 Rs.75,000/- dated 17-10-2022
	The proposed proprietary name / brand name	**NapoEs 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each modified release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm — M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name — Esonyp 20/500mg DR Tablet	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
21.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road,

		Sheikhupura.
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 6023 dated 03-03-2023 Rs.75,000/- dated 01-11-2022
	The proposed proprietary name / brand name	**Pantowin 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Lyophillized Vial Contains: Pantoprazole Sodium Eq. to Pantoprazole…….40mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Pantoprazole sodium 40mg IV Injection of M/s Sandoz Inc (USFDA approved)
	For generic drugs (me-too status)	NEEGE 40mg Injection of M/s Sami Pharma (Reg # 057832)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm — M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name — PANTO 40mg IV Injection The composition of applied formulation shall not mention "Lyophilized vial".	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter** **Submission of latest GMP inspection report of the manufacturer, conducted within last three years.**	
22.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur**

		Azad Kashmir
	Name, address of Manufacturing site.	M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad.
	GMP status of the manufacturer	Firm has submitted copy of GMP Certificate No. F.3-78/20118-Addl.Dir.(QA&LT-I)-34 dated 24th December, 2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP Certificate No. F.3-78/20118-Addl.Dir.(QA&LT-I)-34 dated 24th December, 2021 confirming availability of Sachet general section
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy. No 1363 dated 16-01-2023 Rs.75,000/- dated 06-01-2023
	The proposed proprietary name / brand name	**Noran 40/1680 mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
	Pharmaceutical form of applied drug	Immediate Release Powder for Oral Suspension in Sachet
	Pharmacotherapeutic Group of (API)	A02BC01, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID (For Suspension; Oral) of Santarus, Inc., San Diego (USFDA Approved).
	For generic drugs (me-too status)	Risek Insta Sachet 40mg + 1680mg of M/s Getz Pharma.
	Name and address of API manufacturer.	Omeprazole: M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Sodium Bicarbonate: CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad has already been approved by Registration Board in its 329th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad Manufacturer firm — M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad Brand Name — EPRACO 40/1680 mg Sachets	

	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
23.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir**
	Name, address of Manufacturing site.	M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad.
	GMP status of the manufacturer	Firm has submitted copy of GMP Certificate No. F.3-78/20118-Addl.Dir.(QA&LT-I)-34 dated 24th December, 2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP Certificate No. F.3-78/20118-Addl.Dir.(QA&LT-I)-34 dated 24th December, 2021 confirming availability of Sachet general section
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 1362 dated 16-01-2023 Rs.75,000/- dated 06-01-2023
	The proposed proprietary name / brand name	**Noran 20/1680 mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole…20mg Sodium Bicarbonate…1680mg
	Pharmaceutical form of applied drug	Immediate Release Powder for Oral Suspension in Sachet
	Pharmacotherapeutic Group of (API)	A02BC01, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID (For Suspension; Oral) of Santarus, Inc., San Diego (USFDA Approved).
	For generic drugs (me-too status)	Risek Insta Sachet 20mg + 1680mg (Reg. No. 58547) of M/s Getz Pharma.
	Name and address of API manufacturer.	Omeprazole: M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Sodium Bicarbonate: CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad has already been approved by Registration Board in its 329th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad Manufacturer firm: M/s Gray's Pharmaceuticals Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad Brand Name: EPRACO 20/1680 mg Sachets	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
24.	Name, address of Applicant / Marketing Authorization Holder	**M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	**M/s English Pharmaceuticals:** Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Evidence of approval of manufacturing facility	**M/s English Pharmaceuticals:** The firm has provided Dry powder injection vials (General) approval.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 5678 dated 28-02-2023 Rs.75,000/- dated 25-08-2022
	The proposed proprietary name / brand name	**Zolapt 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole as sodium-------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg Powder for Solution for Infusion (MHRA)
	For generic drugs (me-too status)	Risek 40 mg IV injection By M/S Getz Pharma
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road,	

	Thokar Niaz Baig, Multan Road, Lahore have already been approved by Registration Board in its 313th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Pharmedic laboratories., 15-16 Km, Multan Road Lahore. Manufacturer firm: M/s English Pharmaceuticals. Indus Link Kattar Band Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Nilcid 40mg Injection	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
25.	Name, address of Applicant / Marketing Authorization Holder	**M/s Avant Pharmaceuticals.** **M-028 H.I.T.E, Lasbela, Balochistan**
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Lyophilized Injectable section
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy. No 8826 dated 31-03-2023 Rs.75,000/- dated 07-11-2022
	The proposed proprietary name / brand name	**Seclo 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole as sodium-------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg IV Injection of M/s Lek Pharmaceuticals (MHRA approved)
	For generic drugs (me-too status)	Risek 40mg IV powder for solution of M/s GETZ Pharma (Reg # 024170)

	Name and address of API manufacturer.	M/s Rajasthan Antibiotics Ltd., Plot no.A-619 & 630, Rico Industrial Area Bhiwadi-301019 Rajasthan, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Islam Pharmaceuticals., 7 km, Pasrur Road, Sialkot. Manufacturer firm: M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Mozole 40mg Injection The composition shall mention "Each Lyophilized Vial contains" since manufacturer had approvalof applied formulation in "Lyophilized vial (Injectable) general section.	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
26.	Name, address of Applicant / Marketing Authorization Holder	**M/s Avant Pharmaceuticals.** **M-028 H.I.T.E, Lasbela, Balochistan**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section..
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 5492 dated 27-02-2023
	Details of fee submitted	Rs.30,000/- dated 21-04-2022
	The proposed proprietary name / brand name	**Tazobac 2.25gm Injection**
	trength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium..... 0.25g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials

	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore has already been approved by Registration Board in its 321st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 321st meeting are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: ARDCIL Injection 2.25g Injection	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
27.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shawan Pharmaceuticals.** **Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Liquid Injectable section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 3531 dated 07-02-2023 Rs.75,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**Bufan 20mg/ml injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Nalbuphine HCl……20mg
	Pharmaceutical form of applied drug	Clear and colourless solution filled in glass ampoules

	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 20mg/ml (USFDA Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: BIONAL Injection 20mg/mL	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter** **Submission of latest GMP inspection report of the manufacturer, conducted within last three years.**	
28.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shawan Pharmaceuticals.** **Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Liquid Injectable section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 5103 dated 22-02-2023 Rs.75,000/- dated 24-10-2022
	The proposed proprietary name / brand name	**Bufan 10mg/ml injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Nalbuphine HCl……10mg
	Pharmaceutical form of applied drug	Clear and colourless solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Morphinan derivatives

	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml (USFDA Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: BIONAL Injection 10mg/mL	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter** **Submission of latest GMP inspection report of the manufacturer, conducted within last three years.**	
29.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	GMP status of the manufacturer	GMP certificate granted on basis of inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	GMP certificate granted on basis of inspection conducted on 02-03-2021 declares availability of Tablet general section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 3118 dated 02-02-2023 Rs.75,000/- dated 01-02-2023
	The proposed proprietary name / brand name	**Terviza 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Terbinafine as HCl…250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Reference to Finished product specifications	USP specification

	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 250mg Tablets by M/s Dr. Reddy's Laboratories (UK) Ltd, MHRA approved
	For generic drugs (me-too status)	Lamisil 250mg Tablet by M/s Novartis Pharma
	Name and address of API manufacturer.	Ami Lifesciences Pvt. Ltd., Block No.82/B, ECP Road, At & Post. Karakhadi, Tal - Padra, Karakhadi - 391 450, Vadodara, Gujarat, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur have already been approved by Registration Board in its 329th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Manufacturer firm: M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Brand Name: Lamical 250 Tablet	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
30.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	GMP status of the manufacturer	GMP certificate granted on basis of inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	GMP certificate granted on basis of inspection conducted on 02-03-2021 declares availability of Tablet general section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 4037 dated 13-02-2023 Rs.75,000/- dated 01-02-2023
	The proposed proprietary name / brand name	**Terviza 125mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Terbinafine as HCl…125mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Reference to Finished product specifications	USP specification

	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 125mg Tablets by M/s Dr. Reddy's Laboratories (UK) Ltd, MHRA approved
	For generic drugs (me-too status)	Lamisil 125mg Tablet by M/s Novartis Pharma
	Name and address of API manufacturer.	Ami Lifesciences Pvt. Ltd., Block No.82/B, ECP Road, At & Post. Karakhadi, Tal - Padra, Karakhadi - 391 450, Vadodara, Gujarat, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur have already been approved by Registration Board in its 329th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Manufacturer firm: M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Brand Name: Lamical 125mg tablet	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
31.	Name, address of Applicant / Marketing Authorization Holder	**M/s Onyx Pharmaceuticals. 30-A, Industrial Estate Mansehra**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 26-02-2020 of M/s Bio-Mark based upon Evaluation conducted on 13-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 12-06-2017 specifying Oral syrup (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 8828 dated 31-03-2023
	Details of fee submitted	Rs.75,000/- dated 09-02-2023
	The proposed proprietary name / brand name	**Sonyx 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl dihydrate…4mg

	Pharmaceutical form of applied drug	Clear to straw coloured syrup filled in amber coloured PET bottle
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Oral Solution **(USFDA** Approved)
	For generic drugs (me-too status)	Zofran Syrup by GSK
	Name and address of API manufacturer.	Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSS DC Industrial Estate, Doddaballapur, Banglore, Karnata India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm: M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot Manufacturer firm: M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore Brand Name: Aptron Syrup 4mg/5ml	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
32.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	GMP status of the manufacturer	The firm has submitted copy of panel inspection report dated 20-02-2019 in which the panel recommended grant of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of change of section letter in which the change of Tablet (psychotropic) section to Tablet (General) section was recommended by CLB in its 222nd meeting.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 6419 dated 07-03-2023 Rs.75,000/- dated 01-12-2022
	The proposed proprietary name / brand name	**Vonozen 10mg Tablet**
	Strength / concentration of drug of Active	Each Film Coated Tablet Contains:

	Pharmaceutical ingredient (API) per unit	Vonoprazan as Fumarate…10mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blokers (PCAB)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Takecab tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved
	For generic drugs (me-too status)	Vonseca tablet by M/s Tabros, Karachi
	Name and address of API manufacturer.	Ami Life Sciences Pvt Ltd. Block No. 82/B, ECP Road, AT & Post. Karakhadi, Tal-Padra Karakhadi-391 450 District Vadodara Gujrat State India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Manufacturer firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Brand Name — Vonozen 10mg Tablet	
	Decision:Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
33.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	GMP status of the manufacturer	The firm has submitted copy of panel inspection report dated 20-02-2019 in which the panel recommended grant of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of change of section letter in which the change of Tablet (psychotropic) section to Tablet (General) section was recommended by CLB in its 222nd meeting.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 3123 dated 02-02-2023 Rs.75,000/- dated 01-12-2022

	The proposed proprietary name / brand name	**Vonozen 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…20mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blokers (PCAB)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Takecab tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved
	For generic drugs (me-too status)	Vonseca tablet by M/s Tabros, Karachi
	Name and address of API manufacturer.	Ami Life Sciences Pvt Ltd. Block No. 82/B, ECP Road, AT & Post. Karakhadi, Tal-Padra Karakhadi-391 450 District Vadodara Gujrat State India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Manufacturer firm — M/s Weather Folds Pharmaceuticals Plot # 69, Phase-II, Industrial Estate, Hattar Brand Name — Vonozen 20mg Tablet	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
34.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	GMP status of the manufacturer	GMP certificate granted on basis of inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	GMP certificate granted on basis of inspection conducted on 02-03-2021 declares availability of Tablet general section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 2256 dated 24-01-2023 Rs.75,000/- dated 15-12-2022
	The proposed proprietary name / brand name	**Vonolet 10mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…10mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blokers (PCAB)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved
	For generic drugs (me-too status)	Vonseca 10mg tablet by M/s Tabros, Karachi
	Name and address of API manufacturer.	Ami Lifesciences Pvt. Ltd., Block No.82/B, ECP Road, At & Post. Karakhadi, Tal - Padra, Karakhadi - 391 450, Vadodara, Gujarat, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Manufacturer firm — M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Brand Name — Vonocal 10mg Tablet	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
35.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	GMP status of the manufacturer	GMP certificate granted on basis of inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	GMP certificate granted on basis of inspection conducted on 02-03-2021 declares availability of Tablet general section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 2255 dated 24-01-2023 Rs.75,000/- dated 15-12-2022
	The proposed proprietary name / brand name	**Vonolet 20mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…20mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Potassium-Competitive Acid Blokers (PCAB)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved
	For generic drugs (me-too status)	Vonseca 10mg tablet by M/s Tabros, Karachi
	Name and address of API manufacturer.	Ami Lifesciences Pvt. Ltd., Block No.82/B, ECP Road, At & Post. Karakhadi, Tal - Padra, Karakhadi - 391 450, Vadodara, Gujarat, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur have already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Manufacturer firm — M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur Brand Name — Vonocal 20mg Tablet	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
36.	Name, address of Applicant / Marketing Authorization Holder	**M/s Hoover Pharmaceuticals (Pvt) Ltd.** **Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee	Dy.No 1368 dated 16-01-2023 Rs.75,000/- dated 15-

	submitted	12-2022
	The proposed proprietary name / brand name	**Gatolin 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole as sodium-------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg IV Injection of M/s Lek Pharmaceuticals (MHRA approved)
	For generic drugs (me-too status)	Risek 40mg IV powder for solution of M/s GETZ Pharma (Reg # 024170)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name: Varizole 40mg Injection	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
37.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Copy of GMP certificate No. 103/2020-DRAP (AD-1998036-5147) issued on the basis of inspection conducted on 18/06/2020 is submitted,
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 103/2020-DRAP (AD-1998036-5147) issued on the basis of inspection conducted on 18/06/2020 declares availability of Tablet general section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee	Dy. No 1376 dated 16-01-2023 Rs.75,000/- dated

	submitted	20-12-2022
	The proposed proprietary name / brand name	**Azilsa 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Èach Tablet Contains: Azilsartan Medoxomil Potassium as Azilsartan Medoxomil..... 40mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Hypertensive
	Reference to Finished product specifications	In-House specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (40mg, 80mg) by Arbor Pharms LLC, USFDA Approved.
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	M/s CTX Life Sciences Pvt. Ltd., Block No: 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC Sachin, Surat-394 230 Gujarat, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Azila 40mg tablet Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted. Firm shall submit fee of Rs. 7,500 for pre-approval change/correction in drug product specificationsas per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
38.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Copy of GMP certificate No. 103/2020-DRAP (AD-1998036-5147) issued on the basis of inspection conducted on 18/06/2020 is submitted,
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 103/2020-DRAP (AD-1998036-5147) issued on the basis of inspection conducted on 18/06/2020 declares availability of Tablet general section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 855 dated 10-01-2023 Rs.75,000/- dated 20-12-2022
	The proposed proprietary name / brand name	**Azilsa 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Èach Tablet Contains: Azilsartan Medoxomil Potassium as Azilsartan Medoxomil..... 80mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Hypertensive
	Reference to Finished product specifications	In-House specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (40mg, 80mg) by Arbor Pharms LLC, USFDA Approved.
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	M/s CTX Life Sciences Pvt. Ltd., Block No: 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P, GIDC Sachin, Surat-394 230 Gujarat, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm — M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name — Azila 80mg tablet Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted. Firm shall submit fee of Rs. 7,500 for pre-approval change/correction in drug product specificationsas per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
39.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Copy of GMP certificate No. 103/2020-DRAP (AD-1998036-5147) issued on the basis of inspection conducted on 18/06/2020 is submitted,
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 103/2020-DRAP (AD-1998036-5147) issued on the basis of

		inspection conducted on 18/06/2020 declares availability of Tablet general section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 2739 dated 31-01-2023 Rs.75,000/- dated 30-11-2022
	The proposed proprietary name / brand name	**Nexle 180mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Bempedoic Acid…180mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Bempedoic Acid: Lipid modifying agents, other lipid modifying agents. Adenosine triphosphate citrate lyase (ACL) inhibitor
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Nexlitol Tablets 180mg approved by US-FDA
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal,Visakhapatnam District, Andhra Pradesh, 531021, India (IND).
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore has already been approved by Registration Board in its 322nd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore Brand Name: Bempex Tablet 180mg Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
40.	Name, address of Applicant / Marketing Authorization Holder	**M/s ICU Pharmaceuticals.** **Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road,

		Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Powder suspension section (Cephalosporin).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 5105 dated 22-02-2023 Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Xec-Xim 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)……100mg
	Pharmaceutical form of applied drug	Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax suspension 100mg/5ml **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 100mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan has already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name — CARECEF 100mg/5ml Dry Suspension **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
41.	Name, address of Applicant / Marketing Authorization Holder	**M/s ICU Pharmaceuticals.** **Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur**

		Kehna, Tehsil Sharakpur, District Sheikhupura
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Powder suspension section (Cephalosporin).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 5104 dated 22-02-2023 Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Xec-Xim 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)……200mg
	Pharmaceutical form of applied drug	Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax suspension 200mg/5ml **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan has already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name — CARECEF 200mg/5ml Dry Suspension The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

	The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter	
42.	Name, address of Applicant / Marketing Authorization Holder	**M/s Linta Pharmaceuticals Pvt Ltd.** **Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 7487 dated 15-03-2023 Rs.75,000/- dated 08-03-2023
	The proposed proprietary name / brand name	**CT-X 2gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……2g
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Droncef injection by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Amson Vaccines and Pharma Pvt Ltd. Plot No. 154, Industrial Triangle Kahuta Road Islamabad Manufacturer firm — M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name — Cesod 2gm IV injection Latest GMP inspection report of drug product manufacturer, conducted within last three years, shallbe submitted.	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter.	

	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
43.	Name, address of Applicant / Marketing Authorization Holder	**M/s Linta Pharmaceuticals Pvt Ltd.** **Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 7485 dated 15-03-2023
	Details of fee submitted	Rs.75,000/- dated 08-03-2023
	The proposed proprietary name / brand name	**CT-X 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 250mg powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Droncef injection 250mg by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad have already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat Lahore.	

	Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Snare IV injection Latest GMP inspection report of drug product manufacturer, conducted within last three years, shallbe submitted.	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
44.	Name, address of Applicant / Marketing Authorization Holder	**M/s Linta Pharmaceuticals Pvt Ltd.** **Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 7486 dated 15-03-2023
	Details of fee submitted	Rs.75,000/- dated 08-03-2023
	The proposed proprietary name / brand name	**CT-X 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 500mg powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Droncef injection 500mg by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad have already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Amson Vaccines and Pharma Pvt Ltd. Plot No. 154, Industrial Triangle Kahuta Road Islamabad. Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Cesod 500mg IV injection Latest GMP inspection report of drug product manufacturer, conducted within last three years, shallbe submitted.	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
45.	Name, address of Applicant / Marketing Authorization Holder	**M/s Onyx Pharmaceuticals.** **30-A, Industrial Estate Mansehra**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies liquid ampoule (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 1732 dated 18-01-2023 Rs.75,000/- dated 14-11-2022
	The proposed proprietary name / brand name	**Dorvit Ampoule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Cholecalciferol……5mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Cholecalciferol Injection **(ANSM** France Approved)
	For generic drugs (me-too status)	Novel-D Injection by Danas Pharma (Reg #073183)

	Name and address of API manufacturer.	Fermenta Biotech Limited. Village Takoli P.O. Nagwain, Dist Mandi Himachal Pradesh India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Cherwel Pharmaceuticals (Pvt) Ltd. Plot No. 20, Phase 4, Hattar-Industrial Estate, KPK. Manufacturer firm: M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad. Brand Name: Sunray Injection 5mg/mL Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
46.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio-next Pharmaceuticals.** **Plot No. 50, Street No. S-10, RCCI, Rawat**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies liquid ampoule (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 29749 dated 20-10-2022 Rs.75,000/- dated 14-10-2021
	The proposed proprietary name / brand name	**D-Next Ampoule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Cholecalciferol……5mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's specs

	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Cholecalciferol Injection **(ANSM** France Approved)
	For generic drugs (me-too status)	Novel-D Injection by Danas Pharma (Reg #073183)
	Name and address of API manufacturer.	Fermenta Biotech Limited. Village Takoli P.O. Nagwain, Dist Mandi Himachal Pradesh India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad. have already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Cherwel Pharmaceuticals (Pvt) Ltd. Plot No. 20, Phase 4, Hattar-Industrial Estate, KPK. Manufacturer firm: M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad. Brand Name: Sunray Injection 5mg/mL Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
47.	Name, address of Applicant / Marketing Authorization Holder	**M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore**
	Name, address of Manufacturing site.	M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.
	GMP status of the manufacturer	The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020
	Evidence of approval of manufacturing facility	The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 1369 dated 16-01-2023 Rs.75,000/- dated 15-12-2022
	The proposed proprietary name / brand name	**Essopel 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium -------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor

	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Nexium 40mg IV powder for solution of M/s GETZ Pharma
	Name and address of API manufacturer.	Sterile India Pvt Ltd. Plot No. 100, Sec-56 Phase-4, Kundli Sonipat (Haryana) India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Manufacturer firm: M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura. Brand Name: Esovar 40mg Injection Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
48.	Name, address of Applicant / Marketing Authorization Holder	**M/s ICU Pharmaceuticals.** **Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Powder Injection section (General).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 8792 dated 30-03-2023 Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Eso-Rose 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium -------- 40 mg
	Pharmaceutical form of applied drug	Powder for injection/infusion (Pre-Lyophilized)

	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Nexium 40 mg IV injection By M/S Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Scie nces8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm — M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name — Esogen 40mg Injection The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
49.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nicholas Pharmaceuticals.** **Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 472 dated 05-01-2023 Rs.75,000/- dated 12-10-2022
	The proposed proprietary name / brand name	**Enrox-E 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each modified release tablet contains:

		Esomeprazole (as magnesium trihydrate) as IR …… 20mg Naproxen as enteric coated core ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	For generic drugs (me-too status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/500mg DR Tablet	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
50.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nicholas Pharmaceuticals.** **Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of the manufacturer	GMP inspection conducted on 10/12/2020
	Evidence of approval of manufacturing facility	GMP inspection conducted on 10/12/2020 Tablet (General & General Antibiotic) section approved.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 35681 dated 08-12-2022 Rs.75,000/- dated 17-10-2022
	The proposed proprietary name / brand name	**Enrox-E 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each modified release tablet contains: Esomeprazole (as magnesium trihydrate) as IR …….. 20mg Naproxen as enteric coated core ……. 375mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Esomeprazole: Proton Pump Inhibitors Naproxen: Anti-inflammatory and antirheumatic products, non-steroids. Propionic acid derivatives.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	For generic drugs (me-too status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Name and address of API manufacturer.	Esomeprazole: Metrochem API Private Ltd. India flat No 302, Bhanu Enclave , Sunder Nagar, Erragada, Hyderabad , India. Naproxen: Divis laboratories Limited India 1-72/23(P)/DIVIS/303, Divi towers, cyber hills, Gachibowli, Hyderabad-500 032, Telangana, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan have already been approved by Registration Board in its 324th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Esonyp 20/375mg DR Tablet	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
51.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akhai Pharmaceuticals Pvt Ltd.** **Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan

	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Hydrocortisone injection section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 2607 dated 27-01-2023
	Details of fee submitted	Rs.75,000/- dated 22-11-2022
	The proposed proprietary name / brand name	**Hydrocortisone 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 500 mg
	Pharmaceutical form of applied drug	White to off White color, Lyophilized, Sterile Powder filled in Glass Vial as 1's Injection with 2mL Water for Injection further packed in Card board Unit Carton along with Leaflet.
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cortizone injection by Global pharma
	Name and address of API manufacturer.	Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India

Evaluation by PEC:

The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan has already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	**BIOCORT 500 mg Injection**

Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.

Latest GMP inspection report of drug product manufacturer, conducted within last three years, shallbe submitted.

Decision: Approved.

	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
52.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akhai Pharmaceuticals Pvt Ltd.** **Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Hydrocortisone injection section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 2390 dated 25-01-2023
	Details of fee submitted	Rs.75,000/- dated 22-11-2022
	The proposed proprietary name / brand name	**Hydrocortisone 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 250 mg
	Pharmaceutical form of applied drug	White to off White color, Lyophilized, Sterile Powder filled in Glass Vial as 1's Injection
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cortizone injection by Global pharma
	Name and address of API manufacturer.	Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan has already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: **BIOCORT 250 mg Injection** **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan** Latest GMP inspection report of drug product manufacturer, conducted within last three years, shallbe submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
53.	Name, address of Applicant / Marketing Authorization Holder	**M/s Islam Pharmaceuticals.** **7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	GMP status of the manufacturer	GMP certificate issued on the basis of inspection conducted on 17& 18-01-2019
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 17& 18-01-2019, declares availability of Liquid injectable vial & ampoule section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 5098 dated 22-02-2023 Rs.75,000/- dated 11-01-2023
	The proposed proprietary name / brand name	**Feroxy 50mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Iron as Ferric Carboxymaltose…50mg/ml
	Pharmaceutical form of applied drug	IV Liquid injection
	Pharmacotherapeutic Group of (API)	Iron preparation
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK

	For generic drugs (me-too status)	Ferotox 50mg/ml Injection of M/s Wilshire Laboratories Reg.# 108356
	Name and address of API manufacturer.	M/s Nanjing Hancer Pharmaceutical Co., Ltd., China, No. 18 Hichang Road, Lishui Economi Technlogical Development one Jiangsu, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore **have** already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Aptcure Pvt Ltd. 8- Pharma City, 30 km Multan Road, Lahore Manufacturer firm: M/s English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Greeninject 50mg/ml Injection Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted before issuance of registration letter. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
54.	Name, address of Applicant / Marketing Authorization Holder	**M/s World Biz Pharmaceuticals Company. 340, Phase II, Industrial Estate, Multan, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Soft gelatin Capsule (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 48 dated 02-01-2023 Rs.75,000/- dated 09-12-2022
	The proposed proprietary name / brand name	**Isomax 20mg Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Yellow color soft gel capsule containing yellow color liquid
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Isotretinoin 20 mg soft capsules (MHRA Approved)

	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Name and address of API manufacturer.	Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Changqin China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: BIOTAN 20mg Capsule **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan** Latest GMP inspection report of drug product manufacturer, conducted within last three years, shallbe submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
55.	Name, address of Applicant / Marketing Authorization Holder	**M/s Dyson Research Laboratories Pvt Ltd.** **28 km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Soft gelatin Capsule (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 607 dated 06-01-2023 Rs.75,000/- dated 23-11-2022
	The proposed proprietary name / brand name	**Acesoft 20mg Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Yellow color soft gel capsule containing yellow color liquid
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	Proposed Pack size & Unit price	As per SRO

	The status in reference regulatory authorities	Isotretinoin 20 mg soft capsules (MHRA Approved)
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Name and address of API manufacturer.	Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Changqin China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Scie nces8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: BIOTAN 20mg Capsule **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan** Latest GMP **inspection** report of drug product manufacturer, conducted within last three years, shallbe submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
56.	Name, address of Applicant / Marketing Authorization Holder	**M/s Jenner Pharmaceuticals Pvt Ltd.** **26-km, Lahore Sharaqpur Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Soft gelatin Capsule (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 606 dated 06-01-2023 Rs.75,000/- dated 20-12-2022
	The proposed proprietary name / brand name	**Jentret 20mg Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Yellow color soft gel capsule containing yellow color liquid
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	Proposed Pack size & Unit price	As per SRO

	The status in reference regulatory authorities	Isotretinoin 20 mg soft capsules (MHRA Approved)
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Name and address of API manufacturer.	Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Changqin China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: BIOTAN 20mg Capsule **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan** Latest GMP inspection report of drug product manufacturer, conducted within last three years, shallbe submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
57.	Name, address of Applicant / Marketing Authorization Holder	**M/s Onyx Pharmaceuticals.** **30-A, Industrial Estate Mansehra**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1733 dated 18-01-2023
	Details of fee submitted	Rs.75,000/- dated 14-11-2022
	The proposed proprietary name / brand name	**Mytox 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials

	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad has already been approved by Registration Board in its 296th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. Manufacturer firm: M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. Brand Name: **MENEPOR 500 mg Injection IV** Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
58.	Name, address of Applicant / Marketing Authorization Holder	**M/s Onyx Pharmaceuticals.** **30-A, Industrial Estate Mansehra**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1734 dated 18-01-2023
	Details of fee submitted	Rs.75,000/- dated 14-11-2022
	The proposed proprietary name / brand name	**Mytox 1gm IV Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.

Evaluation by PEC:

The applied product to be manufactured by M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad has already been approved by Registration Board in its 296th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Manufacturer firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Brand Name	MENEPOR 1gmInjection IV

Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.

Decision: Approved.

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

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

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

59.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited.B-23, S.I.T.E. Karachi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Carbapenem Injection section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale

		Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 6370 dated 06-03-2023
	Details of fee submitted	Rs.75,000/- dated 10-02-2023
	The proposed proprietary name / brand name	**Mi-Penem 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: **Merogen 500 mg Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
60.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited. B-23, S.I.T.E. Karachi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.

	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Carbapenem Injection section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 6369 dated 06-03-2023
	Details of fee submitted	Rs.75,000/- dated 10-02-2023
	The proposed proprietary name / brand name	**Mi-Penem 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved productare as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: **Merogen 1gm Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
61.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore

	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1367 dated 16-01-2023
	Details of fee submitted	Rs.75,000/- dated 11-01-2023
	The proposed proprietary name / brand name	**Ropen 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.

Evaluation by PEC:

The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
Manufacturer firm	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
Brand Name	**ROPEN 500 mg Injection IV**

Decision: Approved.

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

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

	The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter	
62.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1366 dated 16-01-2023
	Details of fee submitted	Rs.75,000/- dated 11-01-2023
	The proposed proprietary name / brand name	**ROPEN 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter.**	
63.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals.** **Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3121 dated 02-02-2023
	Details of fee submitted	Rs.75,000/- dated 25-01-2023
	The proposed proprietary name / brand name	**Ropen 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)

	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 500 mg Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
64.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals.** **Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3662 dated 08-02-2023
	Details of fee submitted	Rs.75,000/- dated 25-01-2023
	The proposed proprietary name / brand name	**ROPEN 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials

	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
65.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 7085 dated 10-03-2023

	Details of fee submitted	Rs.75,000/- dated 24-02-2023
	The proposed proprietary name / brand name	**ROPEN 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter r.**	
66.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals.** **Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3121 dated 02-02-2023
	Details of fee submitted	Rs.75,000/- dated 25-01-2023
	The proposed proprietary name / brand name	**Ropen 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 500 mg Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
67.	Name, address of Applicant / Marketing Authorization Holder	**M/s Weather Folds Pharmaceuticals.** **Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Evidence of approval of manufacturing facility	New DML granted vide license No. 000951 dated 23.12.2021specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3662 dated 08-02-2023
	Details of fee submitted	Rs.75,000/- dated 25-01-2023
	The proposed proprietary name / brand name	**ROPEN 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore has already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Manufacturer firm: M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore Brand Name: **ROPEN 1GM Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
68.	Name, address of Applicant / Marketing Authorization Holder	**M/s Swera Pharmaceuticals.** **Plot No. 27, Street No. S-4, RCCI-Rawat,**

		Islamabad
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued on 24-05-2021 based on the inspection dated 30-04-2021. The certificate is valid till 29-04-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 26-09-2019 specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 845 dated 10-01-2023
	Details of fee submitted	Rs.75,000/- dated 06-01-2023
	The proposed proprietary name / brand name	**Meromax 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Manufacturer firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Brand Name: DEWNEM Injection 1gm Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter** **Submission of latest GMP inspection report of the manufacturer, conducted within last three years.**	
69.	Name, address of Applicant / Marketing Authorization Holder	**M/s Swera Pharmaceuticals.** **Plot No. 27, Street No. S-4, RCCI-Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued on 24-05-2021 based on the inspection dated 30-04-2021. The certificate is valid till 29-04-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 26-09-2019 specifying grant of dry powder injection (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 844 dated 10-01-2023
	Details of fee submitted	Rs.75,000/- dated 06-01-2023
	The proposed proprietary name / brand name	**Meromax 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials

	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No. 88, Yangzi Road, Shijiazhuang Economic and Technological Development Zone, Hebei Province PR. China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan has already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Manufacturer firm: M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan Brand Name: DEWNEM Injection 500mg	
	Latest GMP inspection report of drug product manufacturer, conducted within last three years, shall be submitted.	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter** **Submission of latest GMP inspection report of the manufacturer, conducted within last three years.**	
70.	Name, address of Applicant / Marketing Authorization Holder	**M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate valid up to 12-01-2025
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate specifying availability of Liquid Injection Vial section (General).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale

		Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3532 dated 07-02-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2022
	The proposed proprietary name / brand name	**MetroWel Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Metronidazole .....500 mg
	Pharmaceutical form of applied drug	Sterile Solution for intravenous infusion
	Pharmacotherapeutic Group of (API)	Nitro-imidazole Antimicrobials
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Flagyl Infusion of Sanofi Aventis
	Name and address of API manufacturer.	M/s Hubei Hong Yuan Pharmaceuticals technology Co. Ltd. Address: 126 # Dabeishan Road, Industrial and Economic Development Zone Luotian County, Huanggang Cirt, Hubei, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Well & Well Pharma (Pvt) Ltd. Plot No.7 Street S-8 National Industrial Zone RCCI Rawat Manufacturer firm: M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Brand Name: MetroWel Infusion	
	Decision: Deferred for the clarification of applying in two different container/closure systems as the same formulation is already registered in glass vial.	
71.	Name, address of Applicant / Marketing Authorization Holder	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate valid up to 12-01-2025
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate specifying availability of Liquid Injection Vial section (General).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28256 dated 05-10-2022
	Details of fee submitted	Rs.75,000/- dated 30-09-2022

	The proposed proprietary name / brand name	**Metromac 500mg Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Metronidazole .....500 mg
	Pharmaceutical form of applied drug	Sterile Solution for intravenous infusion
	Pharmacotherapeutic Group of (API)	Nitro-imidazole Antimicrobials
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Flagyl Infusion of Sanofi Aventis
	Name and address of API manufacturer.	M/s Hubei Hong Yuan Pharmaceuticals technology Co. Ltd. Address: 126 # Dabeishan Road, Industrial and Economic Development Zone Luotian County, Huanggang Cirt, Hubei, China

Evaluation by PEC:

The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Well & Well Pharma (Pvt) Ltd. Plot No.7 Street S-8 National Industrial Zone RCCI Rawat
Manufacturer firm	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	MetroWel Infusion

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.registration application

72.	Name, address of Applicant / Marketing Authorization Holder	**M/s Siam Pharmaceuticals.** **217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 33631 dated 22-11-2022
	Details of fee submitted	Rs.75,000/- dated 17-11-2022
	The proposed proprietary name / brand name	**Meropen 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad has already been approved by Registration Board in its 296th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. Manufacturer firm: M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. Brand Name: **MENEPOR 500 mg Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
73.	Name, address of Applicant / Marketing Authorization Holder	**M/s Siam Pharmaceuticals.** **217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).

	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 33632 dated 22-11-2022
	Details of fee submitted	Rs.75,000/- dated 17-11-2022
	The proposed proprietary name / brand name	**Meropen 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad has already been approved by Registration Board in its 296th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. Manufacturer firm: M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. Brand Name: MENEPOR 1gmInjection IV	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
74.	Name, address of Applicant / Marketing Authorization Holder	**M/s Demont Research Laboratories.** **20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.

	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Soft gelatin Capsule (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 37705 dated 26-12-2022 Rs.75,000/- dated 18-11-2022
	The proposed proprietary name / brand name	**Isovin 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…20mg
	Pharmaceutical form of applied drug	Yellow color soft gel capsule containing yellow color liquid
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Isotretinoin 20 mg soft capsules (MHRA Approved)
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Name and address of API manufacturer.	Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Changqin China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Scie nces8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 312th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Manufacturer firm: M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi Brand Name: BIOTAN 20mg Capsule	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
75.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nabiqasim Industries Pvt Ltd.** **17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Stallion Pharmaceuticals:** Firm has submitted GMP

		certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection dated 22-09-2020 for M/s Stallion Pharma specifying dry powder injection Vial (Penicillin) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24973 dated 02-09-2022
	Details of fee submitted	Rs.75,000/- dated 28-06-2022
	The proposed proprietary name / brand name	**Tazicillin 4.5gm IV Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium..... 0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Shandong (Previously Qilu) Anxin Pharmaceutical Co., Ltd. 10678 Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan has already been approved by Registration Board in its 308th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm — M/s Healthtek (Pvt.) Limited. Plot No. 14, Sector 19, Korangi Industrial Area Karachi Manufacturer firm — M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan Brand Name — PITZO Injection 4.5g Injection	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
76.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nabiqasim Industries Pvt Ltd.** **17/24, Korangi Industrial Area, Karachi, Pakistan**

	Name, address of Manufacturing site.	M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection dated 22-09-2020 for M/s Stallion Pharma specifying dry powder injection Vial (Penicillin) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24972 dated 02-09-2022
	Details of fee submitted	Rs.75,000/- dated 28-06-2022
	The proposed proprietary name / brand name	**Tazicillin 2.25gm IV Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium..... 0.25g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Shandong (Previously Qilu) Anxin Pharmaceutical Co., Ltd. 10678 Wenliang Road, Dongjia Town, Licheng District, Jinan, Shandong, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan has already been approved by Registration Board in its 308th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 321st meeting are as follows: Applicant firm — M/s Healthtek (Pvt.) Limited. Plot No. 14, Sector 19, Korangi Industrial Area Karachi Manufacturer firm — M/s. Stallion Pharmaceuticals (Pvt.) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan Brand Name — PITZO Injection 2.25 Injection	
	Decision: Approved.	

	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
77.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000783 of M/s Stallion Pharma Islamabad dated 08-02-2016 specifying dry powder injection Vial (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23830 dated 23-08-2022
	Details of fee submitted	Rs.75,000/- dated 28-06-2022
	The proposed proprietary name / brand name	**Merobact IV 500mg Sterile Dry Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows: Applicant firm: M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25 Sector 20, Korangi Industrial Area Karachi. Manufacturer firm: M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan Brand Name: **ASPINEM 500 mg Injection IV**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	
78.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000783 of M/s Stallion Pharma Islamabad dated 08-02-2016 specifying dry powder injection Vial (carbapenem) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23831 dated 23-08-2022
	Details of fee submitted	Rs.75,000/- dated 28-06-2022
	The proposed proprietary name / brand name	**Merobact IV 1gm Sterile Dry Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gm (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan has already been approved by Registration Board in its 323rd meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	
	Applicant firm: M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25 Sector 20, Korangi Industrial Area Karachi. Manufacturer firm: M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan Brand Name: **ASPINEM 1gm Injection**	
	Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**	

Registration applications to be considered on Priority as per 257th meeting of registration board

The Board in its 257th meeting decided that drugs for treatment of cancer, viral diseases, thalassemia, immunosuppressant, vaccine and sera, new molecules / formulations, blood factors and bags will be given priority consideration.

79.	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd**
	Details of Drug Sale License of importer	**License No:01-374-0006-96845D** **Address:** 36-A, PSIC, SIE, Taxila, Rawalpind, Pakistan **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore, **Validity:** 04-08-2024 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s HBT Labs, Inc., 536 Vanguard Way, Brea, CA 92821 United States of America
	Name, address of manufacturer(s)	M/s Nannjing King-friend Biochemical Pharmaceutical Co., Ltd. No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China
	Name of exporting country	--

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 34UN-R5KT) valid till 8-11-2025 US FDA for Fulvestrant injection 250mg/5ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. **The name of importing country on CoPP is mentioned as Pakistan.** Applicant of COPP is Guopinzhao, 8384 Scarlet glen ct, Millersville, MD 21108 United States of America
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from M/s Nannjing King-friend Biochemical Pharmaceutical Co., Ltd. No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China. The letter appoints M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpind, Pakistan to register their products in Pakistan. The authorization letter isissued dated 16-05-2023.
	Status of the applicant	Manufacturer ☒ Importer Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import Buk import and local repackaging Buk import and local repackaging for export purpose only
	Tracking ID and date of submission	XDR-EYQ-QYBV dated 23-11-2023
	Details of fee submitted	PKR 75000/- 17-11-2023
	The proposed proprietary name / brand name	**Festrant Injection 250mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe contains: Fulvestrant ……. 250mg/5ml
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Estrogen receptor antagonists. (L02BA03) with following indications: Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy, or HR-positive advanced breast cancer in postmenopausal women with diseaseprogression following endocrine therapy.
	Reference to Finished product specifications	In house
	Proposed Pack size	2 single dose pre- filled syringe- 5 ml per unit carton.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**US FDA** Approved.

	For generic drugs (me-too status)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Sinopep-Allsino Biopharmaceutical Co., Ltd. No. 28, Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province, 222000, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25 ℃±2 / 60%± 5% RH. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has comparative studies gaianst Fulvestrant Injection of M/s Astrazeneca Pharmaceuticals LP.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP Type I glass type syringes Brominated Butyl Plunger Stopper /5mL
	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 25ºC ±2ºC / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5ºC ±3ºC / The real time stability study data for 3 batches is for 18 months only.

Evaluation by PEC:

Section no.	Obsrvations	Firm's response

	• As per submitted COPP the market authorisation of the applied drug product is M/s HBT Labs, Inc., 536 Vanguard Way, Brea, CA 92821 United States of America, while the letter of Authporisation has been submitted form the drug product manufacturer i.e., M/s Nannjing King-friend Biochemical Pharmaceutical Co., Ltd. No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, shall be submitted in this regard. Clarifcation shall be submitted regarding the country of origin for the applied product i..e, drug product will be exported form which the submitted COPP has been issued from US FDA while the letter of authorisation has been granted by M/s Nannjing King-friend Biochemical Pharmaceutical Co., Ltd. China.	The country of origin for the applied product is China. M/s Nanjing King-friend Biochemical Pharmaceutical Co., Ltd., situated at No. 16 Xuefu Road, Nanjing, China, is the manufacturer of this drug product specifically intended for export to Pakistan. The aforementioned manufacturer, M/s Nanjing King-friend Biochemical Pharmaceutical Co., Ltd., in China, has furnished a letter of authorization to Lab Diagnostic Systems (SMC) Pvt Ltd for this purpose. A Certificate of Pharmaceutical Product (COPP) has been issued bythe US Food and Drug Administration (FDA) forthis product, validating its compliance with regulatory standards. M/s HBT Labs,Inc. is the market authorization for this product in United States of America.
Decision: Approved as per policy of inspection of manufacturer abroad. **Registration letter will be issued upon submission of clarification that weather the product will be imported from China or USA as according to submitted COPP the market authorisation of the applied drug product is M/s HBT Labs, Inc., 536 Vanguard Way, Brea, CA 92821 United States of America, while the letter of Authporisation has been submitted from the drug product manufacturer i.e., M/s Nannjing King-friend Biochemical Pharmaceutical Co., Ltd. No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China**		

80.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Macter International Limited F-216, S.I.T.E, Karachi, Pakistan.**
	Name, address of Manufacturing site.	M/s Pharmasol (Pvt.) Ltd. Plot No. 549, Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate issued basis of inspection conducted on 22-08-2022.
	Evidence of approval of manufacturing facility	Tablet Section (Anti-cancer Human), approval granted by DRAP (Central Licensing Board) vide letter No. F. 1-17/2005-Lic, dated: 22-12-2017.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission & Details of fee submitted	Dy.No 24553 dated 09-10-2023 Rs.75,000/- dated 08-09-2023
	The proposed proprietary name / brand name	**Katbin Tablets 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Capecitabine……500mg
	Pharmacotherapeutic Group of (API)	Tablet
	Pharmaceutical form of applied drug	Antineoplastic Agent
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10's, 50's & 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xeloda (Capecitabine) Tablets 500mg Approved by FDA
	For generic drugs (me-too status)	Xeloda tablets of M/s Roche
	Name and address of API manufacturer.	Guang'an Kingday Pharma & Chem Co., Ltd Wusheng Industrial Park, Guang'an 638400, Sichuan Province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/totalimpurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substance as per Zone-IV a conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Comparative Dissolution Profile & Pharmaceutical Equivalence of their product against the reference product Xeloda tablet 500mg manufactured by M/s Roche.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Guang'an Kingday Pharma & Chem Co., Ltd Wusheng Industrial Park, Guang'an 638400, Sichuan Province, P.R.China		
API Lot No.	Ca-191001		
Description of Pack (Container closure system)	Alu-Alu/PVC		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MI001	MI002	MI003
Batch Size	50000 Tablets	50000 Tablets	50000 Tablets
Manufacturing Date	09-2019	02-2020	06-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML no. Chuan 20160419 issued by Sichuan Drug Administration valid till 21-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy ofcommercial inovice # \KSDS201902020 specifying 50Kg of Capecitabine, attested by AD (I&E) DRAP, Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

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

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

Deferred cases:

81.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate dated 07-03-2023 based on inspection conducted on 22-02-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 18-06-2021 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 7173 dated 13-03-2023
	Details of fee submitted	PKR 30,000/- Dated 12-12-2022
	The proposed proprietary name / brand name	**CONSTIPAS 2MG TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate 2.64mg eq. to Prucalopride…….2mg
	Pharmacotherapeutic Group of (API)	Anti-constipating agent (Serotonin Type 4 (5-HT4) receptor agonist) WHO ATC code: A06AX05
	Pharmaceutical form of applied drug	Round shape pink color coated tablet plain from both sides, free from capping, chipping, mottling and black particles.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	**7's, 10's, 14's, 28's, 30's, 56's, 60's & 100's.**
	Proposed unit price	As per DPC/DPP 2018
	The status in reference regulatory authorities	Product is registered in **US FDA** with brand Name **"MOTEGRITY"** 2MG TABLET by **TAKEDA PHARMS USA.**
	For generic drugs (me-too status)	**PRU-CIC 2mg** Tablet of Searle company Ltd**.** (Reg #116036)
	Name and address of API manufacturer.	**API manufacturer of Prucalopride Succinate** SYMED LABS LIMITED Unit –VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri Bhuvangiri (Dist) – 508 204, Telangana, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both API at accelerated as well as real time conditions. The real time stability data of Prucalopride conducted at 25±2°C, 60%±5% RH. The stability study data is till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical equivalence and Comparative dissolution profile against Resolor 2 mg Tablet of Janssen-Cilag S.pA., Via C. Janseen, 04100 Borogo S. Michele, Latina, Italy
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**API manufacturer of Prucalopride Succinate** SYMED LABS LIMITED Unit –VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri Bhuvangiri (Dist) – 508 204, Telangana, INDIA.		
API Lot No.	6PCS 0020121		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	<u>Proposed</u> Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12,18, 24 (Months) <u>Completed</u> Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	(070B22)	(071B22)	(072B22)
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	April-2022	April-2022	April-2022
Date of Initiation	28-04-2022	28-04-2022	28-04-2022
No. of Batches	03		

82.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 07-03-2023 based on inspection conducted on 22-02-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 18-06-2021 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 7172 dated 13-03-2023
	Details of fee submitted	PKR 30,000/- Dated 12-12-2022
	The proposed proprietary name / brand name	**CONSTIPAS 1MG TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate 1.32mg eq. to Prucalopride… 1mg
	Pharmacotherapeutic Group of (API)	Anti-constipating agent (Serotonin Type 4 (5-HT4) receptor agonist) WHO ATC code: A06AX05
	Pharmaceutical form of applied drug	Round shape pink color coated tablet plain from both sides, free from capping, chipping, mottling and black particles.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	**7's, 10's, 14's, 28's, 30's, 56's, 60's & 100's.**
	Proposed unit price	As per DPC/DPP 2018
	The status in reference regulatory authorities	Product is registered in **US FDA** with brand Name **"MOTEGRITY"** 1MG TABLET by **TAKEDA PHARMS USA**
	For generic drugs (me-too status)	**PRU-CIC 1mg** Tablet of Searle company Ltd**.** (Reg #116035)
	Name and address of API manufacturer.	**API manufacturer of Prucalopride Succinate** SYMED LABS LIMITED Unit –VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri Bhuvangiri (Dist) – 508 204, Telangana, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both API at accelerated as well as real time conditions. The real time stability data of Prucalopride conducted at 25±2°C, 60%±5% RH. The stability study data is till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and Comparative Dissolution Profile against Resolor 1 mg Tablet of Janssen-Cilag S.pA., Via C. Janseen, 04100 Borogo S. Michele, Latina, Italy
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**API manufacturer of Prucalopride Succinate** SYMED LABS LIMITED Unit –VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri Bhuvangiri (Dist) – 508 204, Telangana, INDIA.
API Lot No.	6PCS 0020121
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	<u>Proposed</u> Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12,18, 24 (Months) <u>Completed</u>

	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	(067B22)	(068B22)	(069B22)
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	April-2022	April-2022	April-2022
Date of Initiation	28-04-2022	28-04-2022	28-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product SciAmpa M 5+850mg Tablets & SciAmpa-M 5+1000mg Tablets which was presented in 316th meeting of Registration Board held on 15nd - 18th March, 2022. According to the report following points were confirmed. □ The firm has 21 CFR compliant HPLC software □ The firm has audit trail reports available. □ The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Prucalopride** Copy of GMP certificate No. **L.Dis.No:98805/TS/ 2022** issued by DRUGS CONTROL ADMINISTRATION Government of Telangana valid till **01/01/2027**.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Prucalopride:** Firm has submitted copy of form 6, Computerized No.(# K-160544823612) issued by DRAP Dated: 11-03-2022, specifying import of 70gms Prucalopride (Batch# 6PCs 0020121)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observations	Firm's response
3.2.P.7	Submitted long term stability studies data of drug substance is not as per Zone Iva.	
3.2.P.8.3	Submit clearance certificate issued by DRAP I&E Office Karachi, for import of Prucalopride.	

Decision of 331st meeting: Deferred for submission of reply to above cited shortcomings.

Firm's reply: Firm has cited the decision of 297th meeting of Registration Board and referrd to the impurity studies performed during drug product stability studies. Mporeover frim has again submitted copy of form 6, Computerized No.(# K-160544823612) issued by DRAP Dated: 11-03-2022, specifying 70gms Prucalopride (Batch# 6PCs 0020121)

Decision: Registration Board approved the applications of Constipas 1mg Tablet & Constipas 2mg Tablet.

	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
83.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	--
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated specifying Tablet (General) section 05/05/2010.
	Status of application	☒ New Drug Product (NDP) Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 19960 dated 07-07-2022
	Details of fee submitted	Rs.75,000/- dated 27-06-2022
	The proposed proprietary name / brand name	**Flopin 5/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as L-Pyroglutamic Acid …..… 5mg Sitagliptin as Phosphate Monohydrate ……. 100mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	--
	Name and address of API manufacturers.	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. **Address:** Fluoride Industrial Park, Fuxin City, Liaoning Province- I23000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description

		of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence & CDP have been established against the innovator Steglujan tablet
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd.		
API Lot No.	Ertugliflozin L-pyroglutamic acid: L-IG-20211005-D01-IG06-01 Sitagliptin Phosphate Monohydrate: L-GWC-20210804-D05-GWC 04-04		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	30-11-2021	30-11-2021	30-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the list of products previously approved with stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 23/08/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of GMP Certificate issued on 24/08/2020 and valid till 23/08/23

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
84.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 17/02/2022 based on inspection conducted on 27/01/2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated specifying Tablet (General) section 05/05/2010.
	Status of application	☒ New Drug Product (NDP) Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 18962 dated 29-06-2022
	Details of fee submitted	Rs.75,000/- dated 27-06-2022
	The proposed proprietary name / brand name	**Flopin 15/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as L-Pyroglutamic Acid …..… 15mg Sitagliptin as Phosphate Monohydrate …..… 100mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	--
	Name and address of API manufacturers.	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Address: Fluoride Industrial Park, Fuxin City, Liaoning Province- I23000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure

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

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd.		
API Lot No.	Ertugliflozin L-pyroglutamic acid: L-IG-20211005-D01-IG06-01 Sitagliptin Phosphate Monohydrate: L-GWC-20210804-D05-GWC 04-04		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	30-11-2021	30-11-2021	30-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the list of products previously approved with stability study data.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 23/08/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of GMP Certificate issued on 24/08/2020 and valid till 23/08/23
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin.	
3.2.S.4	Submit complete analytical method of both drug substances performed from drug product manufacturer.	
3.2.S.4.3	Submit complete analytical method verification study report of both drug substances performed by drug product manufacturer.	
3.2.S.4.4	Date of analysis of Ertugliflozin LPGA declared on COA from M/s Weatherfold is prior to the date of manufacturing of drug substance.	
3.2.P.2.2.1	Submitted Pharmaceutical equivalence report does not include tests of Assay & Dissolution. Detailed CDP report shall be submitted declaring the results for each tablet unit across different time points.	
3.2.P.5.2	Submit complete analytical procedure for dissolution test.	
3.2.P.5.3	Submit complete drug product analytical method validation studies.	
3.2.P.8.3	Submit raw data sheets for dissolution test performed during stability studies. Submit documents for the procurement of APIwith approval from DRAP (in case of import). Submitted HPLC chromatograms does not reveal the US detector wavelength at which the analysis has been performed. Submit audit trail reports of the stability studies performed in HPLC.	

Decision of 331st meeting: Registration Board deferred the cases for submission of reply to the above cited shortcomings.

Firm's reply:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin.	Firm has submitted copy of DML no. 20150233 valid till 20-12-2022.

	3.2.S.4	Submit complete analytical method of both drug substances performed from drug product manufacturer.	Submitted.	
	3.2.S.4.3	Submit complete analytical method verification study report of both drug substances performed by drug product manufacturer.	Submitted.	
	3.2.S.4.4	Date of analysis of Ertugliflozin LPGA declared on COA from M/s Weatherfold is prior to the date of manufacturing of drug substance.	Submitted	
	3.2.P.2.2.1	Submitted Pharmaceutical equivalence report does not include tests of Assay & Dissolution. Detailed CDP report shall be submitted declaring the results for each tablet unit across different time points.	Submitted	
	3.2.P.5.2	Submit complete analytical procedure for dissolution test.	Submitted	
	3.2.P.5.3	Submit complete drug product analytical method validation studies.	Submitted	
	3.2.P.8.3	Submit raw data sheets for dissolution test performed during stability studies. Submit documents for the procurement of APIwith approval from DRAP (in case of import). Submitted HPLC chromatograms does not reveal the UV detector wavelength at which the analysis has been performed. Submit audit trail reports of the stability studies performed in HPLC.	Firm has submitted following: Raw data sheets for stability studies. License to import Ertugliflozin LPGA (0.15Kg) & Sitagliptin 1Kg issued by AD I&E Peshawardated 22-10-2021. Audit trail reports.	

Decision: Registration Board approved the applications of Flopin 5/100 mg Tablet t & Flopin 15/100 mg Tablet.

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

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

85.	Name, address of Applicant / Marketing Authorization Holder	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi – 75730, Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10010 dated 13-04-2023
	Details of fee submitted	PKR 75,000/-: dated 24/02/2023
	The proposed proprietary name / brand name	**EMPOLI TRIO XR 25/5/1000mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin (as immediate release) …25mg Linagliptin (as immediate release) ……. 5mg

		Metformin HCl (as extended release) …….1000mg
	Pharmaceutical form of applied drug	Brown color, Oval shape, film coated tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Oral Blood Glucose Lowering Drugs
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablets, USFDA approved
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	GMP certificate issue date 03-08-2022
	Name and address of API manufacturer.	**Empagliflozin** **Name:**RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China
		Linagliptin **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
		Metformin HCl **Name:**AARTI DRUGS LIMITED **Address**: Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and itsvalidation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurity and related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Empagliflozin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product i.e. **Trijardy XR(25/5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** by performing quality tests (Appearance, Average weight, Water content, Identification, Impurity, Assay, Dissolution, Uniformity of dosage form, Arginine content, Organic impurities and Microbial limit test). CDP has been performed against the same brand that is **Trijardy XR(25/5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** in 0.1N HCl (pH 1.2), Acetate media (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, accuracy, precision including repeatability & Intermediate repeatability, robustness & specificity.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin** **Name:**RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Linagliptin** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl** **Name:**AARTI DRUGS LIMITED **Address**: Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India
API Lot No.	**Empagliflozin:** EGLZRD201905001 **Linagliptin:** L-20200219-D01-L09-01 **Metformin HCl:** MEF/18061175
Description of Pack (Container closure system)	Alu/ Alu
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)

Batch No.		Lab-01	Lab-02	Lab-03
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date		Oct 2020	Oct 2020	Oct 2020
Date of Initiation		Oct 2020	Oct 2020	Oct 2020
No. of Batches		03		
86.	Name, address of Applicant / Marketing Authorization Holder		**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi.**	
	Name, address of Manufacturing site.		M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi – 75730, Pakistan	
	Status of the applicant		☒ Manufacturer Importer Is involved in none of the above (contract giver)	
	Status of application		☒ New Drug Product (NDP) Generic Drug Product (GDP)	
	Intended use of pharmaceutical product		Domestic sale Export sale ☒ Domestic and Export sales	
	Dy. No. and date of submission		Dy.No 10009 dated 13-04-2023	
	Details of fee submitted		Rs.75,000/- dated 24-02-2023	
	The proposed proprietary name / brand name		**EMPOLI TRIO XR 12.5/2.5/1000mg Tablets**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film coated tablet contains: Empagliflozin (as immediate release) …12.5mg Linagliptin (as immediate release) .....2.5mg Metformin HCl (as extended release).....1000mg	
	Pharmaceutical form of applied drug		Pink color, Oval shape, film coated tablet plain on both sides	
	Pharmacotherapeutic Group of (API)		Oral Blood Glucose Lowering Drugs	
	Reference to Finished product specifications		Innovator's	
	Proposed Pack size		As per SRO	
	Proposed unit price		As per SRO	
	The status in reference regulatory authorities		Trijardy XR Tablets, USFDA approved	
	For generic drugs (me-too status)		NA	
	GMP status of the Finished product manufacturer		GMP certificate issue date 03-08.2022	
	Name and address of API manufacturer.		**Empagliflozin** **Name:**RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China	
			Linagliptin **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China	
			Metformin HCl **Name:**AARTI DRUGS LIMITED	

		Address: Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurity and related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Empagliflozin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product i.e. **Trijardy XR(12.5/2.5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** by performing quality tests (Appearance, Average weight, Water content, Identification, Impurity, Assay, Dissolution, Uniformity of dosage form, Arginine content, Organic impurities and Microbial limit test). CDP has been performed against the same brand that is **Trijardy XR(12.5/2.5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** in 0.1N HCl (pH 1.2), Acetate media (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.

	Analytical method validation/verification of product	Method validation studies have submitted including linearity, accuracy, precision including repeatability & Intermediate repeatability, robustness & specificity.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin** **Name:**RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Linagliptin** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl** **Name:**AARTI DRUGS LIMITED **Address**: Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India		
API Lot No.	**Empagliflozin:** EGLZRD201905001 **Linagliptin:** L-20200219-D01-L09-01 **Metformin HCl:** MEF/18061175		
Description of Pack (Container closure system)	Alu/ Alu		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	Oct 2020	Oct 2020	Oct 2020
Date of Initiation	Oct 2020	Oct 2020	Oct 2020
No. of Batches	03		

87.	Name, address of Applicant / Marketing Authorization Holder	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi – 75730, Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10010 dated 13-04-2023
	Details of fee submitted	PKR 75,000/-: dated 24/02/2023
	The proposed proprietary name / brand name	**EMPOLI TRIO XR 10/5/1000mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin (as immediate release) ……10mg

		Linagliptin (as immediate release) ……. 5mg Metformin HCl (as extended release) …….1000mg
	Pharmaceutical form of applied drug	Tan color, Oval shape, film coated tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Oral Blood Glucose Lowering Drugs
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablets, USFDA approved
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	GMP certificate issue date 03-08.2022
	Name and address of API manufacturer.	**Empagliflozin** **Name:**RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China
		Linagliptin **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
		Metformin HCl **Name:**AARTI DRUGS LIMITED **Address**: Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and itsvalidation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurity and related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Empagliflozin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product i.e. **Trijardy XR(10/5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** by performing quality tests (Appearance, Average weight, Water content, Identification, Impurity, Assay, Dissolution, Uniformity of dosage form, Arginine content, Organic impurities and Microbial limit test). CDP has been performed against the same brand that is **Trijardy XR(10/5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** in 0.1N HCl (pH 1.2), Acetate media (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, accuracy, precision including repeatability & Intermediate repeatability, robustness & specificity.

STABILITY STUDY DATA	
Manufacturer of API	**Empagliflozin** **Name:**RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Linagliptin** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl** **Name:**AARTI DRUGS LIMITED **Address**: Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India
API Lot No.	**Empagliflozin:** EGLZRD201905001 **Linagliptin:** L-20200219-D01-L09-01 **Metformin HCl:** MEF/18061175
Description of Pack (Container closure system)	Alu/ Alu
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)

Batch No.		Lab-01	Lab-02	Lab-03
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date		Oct 2020	Oct 2020	Oct 2020
Date of Initiation		Oct 2020	Oct 2020	Oct 2020
No. of Batches		03		
88.	Name, address of Applicant / Marketing Authorization Holder		**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi.**	
	Name, address of Manufacturing site.		M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi – 75730, Pakistan	
	Status of the applicant		☒ Manufacturer Importer Is involved in none of the above (contract giver)	
	Status of application		☒ New Drug Product (NDP) Generic Drug Product (GDP)	
	Intended use of pharmaceutical product		Domestic sale Export sale ☒ Domestic and Export sales	
	Dy. No. and date of submission		Dy. No 6363 dated 06-03-2023	
	Details of fee submitted		Rs.75,000/- dated 04-02-2023	
	The proposed proprietary name / brand name		**EMPOLI TRIO XR 5/2.5/1000mg Tablets**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film coated tablet contains: Empagliflozin (as immediate release) …… 5mg Linagliptin (as immediate release) .....2.5mg Metformin HCl (as extended release).....1000mg	
	Pharmaceutical form of applied drug		Grey color, Oval shape, film coated tablet plain on both sides	
	Pharmacotherapeutic Group of (API)		Oral Blood Glucose Lowering Drugs	
	Reference to Finished product specifications		Innovator's	
	Proposed Pack size		As per SRO	
	Proposed unit price		As per SRO	
	The status in reference regulatory authorities		Trijardy XR Tablets, USFDA approved	
	For generic drugs (me-too status)		NA	
	GMP status of the Finished product manufacturer		GMP certificate issue date 03-08.2022	
	Name and address of API manufacturer.		**Empagliflozin** **Name:**RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China	
			Linagliptin **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China	
			Metformin HCl **Name:**AARTI DRUGS LIMITED	

		Address: Mahendra Industrial Estate Plot No. – 109 –D Road No.29, Sion (East), Mumbai – 400 022. INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurity and related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Empagliflozin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product i.e. **Trijardy XR(5/2.5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** by performing quality tests (Appearance, Average weight, Water content, Identification, Impurity, Assay, Dissolution, Uniformity of dosage form, Arginine content, Organic impurities and Microbial limit test). CDP has been performed against the same brand that is **Trijardy XR(5/2.5/1000mg) Tablet** by **M/s. Boehringer Ingelheim** in 0.1N HCl (pH 1.2), Acetate media (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.

	Analytical method validation/verification of product	Method validation studies have submitted including linearity, accuracy, precision including repeatability & Intermediate repeatability, robustness & specificity.	
STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin** **Name:** RUYUAN HEC Pharm Co., Ltd. **Address**: Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Linagliptin** **Name:** Fuxin Long Rui Pharmaceutical Co.,Ltd **Address** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl** **Name:** AARTI DRUGS LIMITED **Address**: Mahendra Industrial Estate Plot No.211-213, Road No.2, G.I.D.C, Sarigam District, Valsad, Gujarat, India		
API Lot No.	**Empagliflozin:** EGLZRD201905001 **Linagliptin:** L-20200219-D01-L09-01 **Metformin HCl:** MEF/18061175		
Description of Pack (Container closure system)	Alu / Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	Oct 2020	Oct 2020	Oct 2020
Date of Initiation	Oct 2020	Oct 2020	Oct 2020
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of last onsite panel inspection for instant dosage form conducted during last two years i.e. EMPOLI (Empagliflozin) 10mg & 25mg Tablets which was presented in 290th meeting of the registration board & hence approved & registered by registration board Date of inspection: 13th June 2019. The inspection report confirms following points The HPLC software is 21CFR Compliant. Audit trail on the testing reports is available. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin**: Copy of DML No. 20160622 issued by Guangdong Food and Drug Administration valid till 07-10-2026.	

		Linagliptin: Firm has submitted cipy of DML no. 20150233 issued by State Food and Drug Administration valid upto 17-11-2027. **Metformin HCl:** Copy of GMP certificate No. 23064344 issued by Food and Drug Administration Chandhinagar Gujarat state,India valid till 20-06-2026
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin**: Invoice no. WIS190069 (08/10/2019) with received quantity i.e. 500G) with attestation of DRAP dated 29-10-2019 **Linagliptin:** Invoice no.SY20060402-H (04/06/2020) with received quantity i.e. 0.5KG) with attestation of DRAP dated 25-06-2020 **Metformin HCl:** Invoice no. EXP/831AB/18-19 (23/07/2018) with received quantity i.e. 25KG) with attestation of DRAP dated 06-09-2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[II]:

Section#	Observations
	Empagliflozin
3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as " very slightly soluble in water" with reference to the innovator drug product literature.
3.2.S.4.4	Justification shall be submitted for different Assay limits from that applied by drug substance manufacturer.
3.2.S.5	COA of working standard of Empagliflozin used for analysis of drug substance by M/s Sami Pharmaceuticals shall be submitted.
3.2.S.7	Stability summary in section 3.2.S.7.1 declares the long term conditions as 25°C ± 2°C / 60% ± 5%RH, whereas stability data submitted in section 3.2.S.7.3 is as per long term conditions of 30°C ± 2°C / 65% ± 5%RH. Justification shall be submitted for this disparity.
	Linagliptin
3.2.S.1.3	Submitted DMF declare the Polymorphic form as "Not reported", whereas Innovator drug product literature declares that Linagliptin is manufactured as a mixture of anhydrous form A and anhydrous form B. Justification shall be submitted in this regard. Clarification shall be submitted regarding the isomeric form of the drug substance.
3.2.S.4	Justification shall be submitted for not including test of "Enantiomeric purity" in the drug substance specifications.
3.2.S.4.4	Submitted COA of drug substance from both drug product and drug substance manufacturer does not confirm "Enantiomeric purity". Justification shall be submitted in this regard.
3.2.P.1	Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation. Justification shall be submitted for proposed quantity of Arginine in the formulation. Justification shall be submitted on basis of performance based evidence for adding 10% overage of "Empagliflozin" & "Linagliptin" in the applied batch formulation.

3.2.P.2	Justification shall be submitted for proposed quantity of Arginine in the formulation.	
3.2.P.3.5	Submitted process validation protocol does not include details of in-process test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating.	
3.2.P.6	Submit COAs of reference standards/working standards used for analysis of drug product stability batches.	
3.2.P.8.3	Documents confirming import of drug substance shall be submitted. Reconciliation record of drug imported drug substances shall be submitted considering the different combinations and strengths of products applied.	
2.3.R	Justification shall be submitted for the seal coating applied on Metformin HClcore, while referring to the innovator drug product formulation. Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin & Linagliptin at in process stage of active coating. Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing.	

Decision of 331st meetinig: Registration Board deferred the cases for submission of reply to above cited shortcomings.

Firm's reply:

Section#	Observations	Firm's response
	Empagliflozin	
3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as " very slightly soluble in water" with reference to the innovator drug product literature.	Please refer to the attached reference for the solubility of Empagliflozin, which is noted as slightly soluble in water. It's important to note that this solubility information for Empagliflozin is available in the EMA public assessment report of Jardiance Tablet (Empagliflozin Tablet) and is not mentioned in the combination product.
3.2.S.4.4	Justification shall be submitted for different Assay limits from that applied by drug substance manufacturer.	The assay specification is the same for both SAMI and the drug substance manufacturer, which is set at 98 to 102%. Firm has submitted drug substance specificatons from both.
3.2.S.5	COA of working standard of Empagliflozin used for analysis of drug substance by M/s Sami Pharmaceuticals shall be submitted.	Submitted
3.2.S.7	Stability summary in section 3.2.S.7.1 declares the long term conditions as 25°C ± 2°C / 60% ± 5%RH, whereas stability data submitted in section 3.2.S.7.3 is as per long term conditions of 30°C ± 2°C / 65% ± 5%RH. Justification shall be submitted for this disparity.	The drug substance manufacturer initially conducted stability studies at both 25 ± 2°C/60% ±5% RH and 30°C ±2°C/65%±5% RH. Initially, they provided DMF with 25 ± 2°C/60% ±5% RH storage condition data, but upon inquiry, they provided the stability data at 30°C ±2°C/65%±5% RH. Unfortunately, the old data was submitted in section 3.2.S.7.1. Firm has submitted revised pages of DMF.
	Linagliptin	

	3.2.S.1.3	Submitted DMF declare thePolymorphic form as "Not reported", whereas Innovator drug product literature declares that Linagliptin is manufactured as a mixture of anhydrous form A and anhydrous form B. Justification shall be submitted in this regard. Clarification shall be submittedregarding the isomeric form of the drug substance.	Firm has submitted revised documents of DMF for all strengths. We are using the same polymorphic form as the one used by the innovator.	
	3.2.S.4	Justification shall be submitted fornot including test of "Enantiomeric purity" in the drug substance specifications.	Firm has submitted revised drug substance specifications and analytical procedure including test of Chiral purity.	
	3.2.S.4.4	Submitted COA of drug substance from both drug product and drug substance manufacturer does not confirm "Enantiomeric purity". Justification shall be submitted in this regard.	Firm has submitted revised COA of drug substance.	
	3.2.P.1	Justification shall be submitted for theseal coating applied on Metformin HCl core, while referring to the innovator drug product formulation. Justification shall be submitted for proposed quantity of Arginine in the formulation. Justification shall be submitted on basis of performance based evidence for adding 10% overage of "Empagliflozin" & "Linagliptin" in the applied batch formulation.	10% Excess quantity of both APIs (Empagliflozin & Linagliptin) were added in coating dispersion to compensate the process loss faced while the coating operation was being carried out. These extra quantities of API's do not become part of the final film coated tablet and the same is confirmed through the assay and content uniformity results of both APIs. The quantity of Arginine in formulation is concerned, the maximum allowed FDA safe limit of Arginine in oral tablet is 50mg/MDE. Whereas, the quantity of Arginine used in our formulation is 35mg/tablet which is well within the allowable limit. It is a common practice to take overages-of API for drug loading process because the losses are observed/experience during APl coating process, thus extra quantities are added to compensate the process losses Moreover, 10% overage is not fixed, this will be validated during manufacturing of commercial validation batches and the percentage of overage will be finalized based on the trend analysis of assay and content uniformity of validation batches.	

	3.2.P.3.5	Submitted process validation protocol does not include details of in-process test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating.	Firm has submitted re-designed protocol.	
	3.2.P.6	Submit COAs of reference standards/working standards used for analysis of drug product stability batches.	Submitted	
	3.2.P.8.3	Documents confirming import of drug substance shall be submitted. Reconciliation record of drug imported drug substances shall be submitted considering the different combinations and strengths of products applied.	Submitted	
	2.3.R	Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin & Linagliptin at in process stage of active coating. Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing.	Firm has submitted in-process testing report after active coating wherein content of Empagliflozin and Linagliptin has been determined by way of Content uniformity.	

Decision: Registration Board approved the applications of EMPOLI TRIO XR 25/5/1000mg Tablets, EMPOLI TRIO XR 12.5/2.5/1000mg Tablets, EMPOLI TRIO XR 10/5/1000mg Tablets & EMPOLI TRIO XR 5/2.5/1000mg Tablets.

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

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

89.	**Name, address of Applicant / Marketing Authorization Holder**	**Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi..**
	Name, address of Manufacturing site.	Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated:28-07-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-06-2021 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 10558 dated 27-04-2022
	Details of fee submitted	PKR 30,000/- Dated 01-04-2022
	The proposed proprietary name / brand name	**Empagin-M Tablet 12.5mg+1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin… .....12.5mg Metformin HCl 1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Pharmaceutical form of applied drug	Violet color oval shape film coated tablet
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy 12.5mg+500mg Tablets , Boehrimger Ingelhiem Pharmaceuticals
	For generic drugs (me-too status)	Diampa–M by M/s Getz Pharma (Pvt.) Limited (Reg.No. 093084)
	Name and address of API manufacturer. **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.
	Name and address of API manufacturer. **Metformin HCl**	Aarti Drugs Limited. Aarti Drugs Limited. Plot No.211-213,Road No 02 G.I.D.C Sarigam Dist Valsad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance: **Empagliflozin**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance: **Metformin HCl**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, control of materials, 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) **Empagliflozin**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) **Metformin HCl**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Syngardy 12.5mg+500mg Tablet by Boehringer Ingelhiem Pharmaceuticals Firm has submitted CDP results of their product against the innovator's product Synjardy 5mg+500mg Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.		
Manufacturer of API **Metformin HCl**	Aarti Drugs Limited. Plot No.211-213, Road No 02 G.I.D.C Sarigam Dist Valsad		
API Lot No.	08964005-EMP		
API Lot No.Metformin HCl	G/25/2035-MET		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6,9,12,18 & 24 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	167DS04	167DS05	167DS06
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	03-2020	03-2020	03-2020
No. of Batches	03		

Remarks of Evaluator:		
90.	**Name, address of Applicant / Marketing Authorization Holder**	**Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi..**
	Name, address of Manufacturing site.	Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated:28-07-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-06-2021 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10557 dated 27-04-2022
	Details of fee submitted	PKR 30,000/- Dated 01-04-2022
	The proposed proprietary name / brand name	**Empagin-M Tablet 12.5mg+500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin… .....12.5mg Metformin HCl 500mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Pharmaceutical form of applied drug	Violet color oval shape film coated tablet
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy 12.5mg+500mg Tablets , Boehrimger Ingelhiem Pharmaceuticals
	For generic drugs (me-too status)	Sciampa –M by M/s Scilife Pharma (Pvt.) Limited (Reg.No. 103091)
	Name and address of API manufacturer. **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.
	Name and address of API manufacturer. **Metformin HCl**	Aarti Drugs Limited. Aarti Drugs Limited. Plot No.211-213,Road No 02 G.I.D.C Sarigam Dist Valsad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance: **Empagliflozin**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance: **Metformin HCl**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, control of materials, 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) **Empagliflozin**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) **Metformin HCl**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Syngardy 12.5mg+500mg Tablet by Boehringer Ingelhiem Pharmaceuticals Firm has submitted CDP results of their product against the innovator's product Synjardy 5mg+500mg Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.
Manufacturer of API	Aarti Drugs Limited.

Metformin HCl	Plot No.211-213, Road No 02 G.I.D.C Sarigam Dist Valsad		
API Lot No.	08964005-EMP		
API Lot No.Metformin HCl	G/25/2035-MET		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6,9,12,18 & 24 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	174DS04	174DS05	174DS06
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	03-2020	03-2020	03-2020
No. of Batches	03		

Remarks of Evaluator:

91.	**Name, address of Applicant / Marketing Authorization Holder**	**Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi..**
	Name, address of Manufacturing site.	Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated:28-07-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-06-2021 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10555 dated 27-04-2022 Dy. No dated 27-04-2022
	Details of fee submitted	PKR 30,000/- Dated 01-04-2022
	The proposed proprietary name / brand name	**Empagin-M Tablet 5mg+500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…. .....5mg Metformin HCl.....500mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Pharmaceutical form of applied drug	Orange yellow color oval shape film coated tablet
	Reference to Finished product specifications	Manufacturer's Specification

	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy 5mg+500mg Tablets , Boehrimger Ingelhiem Pharmaceuticals
	For generic drugs (me-too status)	Diampa –M by M/s Getz Pharma (Reg.No. 105287)
	Name and address of API manufacturer. **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.
	Name and address of API manufacturer. **Metformin HCl**	Aarti Drugs Limited. Aarti Drugs Limited. Plot No.211-213,Road No 02 G.I.D.C Sarigam Dist Valsad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance: **Empagliflozin**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance: **Metformin HCl**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, control of materials, 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) **Empagliflozin**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) **Metformin HCl**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control,

		process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Syngardy 5mg+500mg Tablet by Boehringer Ingelhiem Pharmaceuticals Firm has submitted CDP results of their product against the innovator's product Synjardy 5mg+500mg Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.		
Manufacturer of API **Metformin HCl**	Aarti Drugs Limited. Plot No.211-213, Road No 02 G.I.D.C Sarigam Dist Valsad		
API Lot No.	08964005-EMP		
API Lot No.Metformin HCl	G/25/2035-MET		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6,12,18 & 24 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	172DS04	172DS05	172DS06
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	03-2020	03-2020	03-2020
No. of Batches	03		

Remarks of Evaluator:

92.	**Name, address of Applicant / Marketing Authorization Holder**	**Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi..**
	Name, address of Manufacturing site.	Aspin Pharma (Pvt.), Ltd Plot No. 10 & 25, Sector 20 Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated:28-07-2022 based on inspection conducted on 13-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-06-2021 specifying Tablet (General) section.

	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 10556 dated 27-04-2022
	Details of fee submitted	Rs.30,000/- dated 01-04-2022
	The proposed proprietary name / brand name	**Empagin-M Tablet 5mg+1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin .....5mg Metformin HCl 1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Pharmaceutical form of applied drug	Orange brown color oval shape film coated tablet
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy 5mg+1000mg Tablets , Boehrimger Ingelhiem Pharmaceuticals
	For generic drugs (me-too status)	Diampa-M 5mg+1000mg by Getz Pharma (Pvt)Ltd (Reg.No. 114327)
	Name and address of API manufacturer. **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.
	Name and address of API manufacturer. **Metformin HCl**	Aarti Drugs Limited. Aarti Drugs Limited. Plot No.211-213,Road No 02 G.I.D.C Sarigam Dist Valsad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance: **Empagliflozin**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance: **Metformin HCl**	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, control of materials, 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) **Empagliflozin**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) **Metformin HCl**	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Syngardy 5mg+1000mg Tablet by Boehringer Ingelhiem Pharmaceuticals Firm has submitted CDP results of their product against the innovator's product Synjardy 5mg+1000mg Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API **Empagliflozin**	Century Pharmaceuticals Ltd. 103-106, G.I.D.C, Estate-Halol 389350 Dist.Panchmahals Gujrat India.		
Manufacturer of API **Metformin HCl**	Aarti Drugs Limited. Plot No.211-213, Road No 02 G.I.D.C Sarigam Dist Valsad		
API Lot No.	08964005-EMP		
API Lot No.Metformin HCl	G/25/2035-MET		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6,12,18 & 24 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	173DS04	173DS05	173DS06
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	01-2020	01-2020	01-2020

Date of Initiation	03-2020	03-2020	03-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. **Empagliflozin**	Firm has submitted copy of GMP Certificate (No. 20011803) dated 09-01-2022 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. **Metformin HCl**	Firm has submitted copy of GMP Certificate (No. 20031933) dated 29-01-2022 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import). **Empagliflozin**	Firm has submitted copy of commercial invoice cleared on 11-01-2019 BY AD I&E Karachi in name of M.s OBS Pakistan Pvt. (Ltd.) specifying 1.5 Kg of Empagliflozin. Firm has also submitted a letter issued by Deputy Director in name of M/s OBS Pakistan dated 28-02-2019 wherein request for one time transfer of materials (including Empagliflozin) from m/s OBS Pakistan to M/s Aspin Pharma.
	Documents for the procurement of API with approval from DRAP (in case of import). **Metformin HCl**	Firm has submitted copy of commercial invoice cleared on 17-12-2019 specifying 1500Kg of Metformin HCI. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section#	Observations
1.6.5	Name of the drug substance manufacturer of Metformin HCl declared in section 1.6.5 is different form that declared in the submitted GMP certificate. Submit valid GMP certificate/DML of the drug substance manufacturer of Metformin HCl.
3.2.S.4.1	Justification shall be submitted for not including test of "particle size", in the submitted drug substance specifications of Empagliflozin, as recommended by innovator literature.
3.2.S.4.2	Drug substance analytical procedure for Empagliflozin shall be submitted from both drug substance manufacturer and M./s Aspin Pharma.
3.2.S4.3	Analytical method verification studies performed by M./s Aspin pharma, shall be submitted for both drug substances.
3.2.S.4.4	COA of the relevant batch of Empagliflozin, used for manufacturing of trial bathes shall be submitted form Drug substance manufacturer. Drug substance manufacturer has declared metformin HCl as of BP grade whereas COA of Metformin HCl submitted from M.s Aspin Pharma reveals analysis as per USP. Justification shall be submitted in this regard.

	3.2.P.2.2.1	Justification shall be submitted for applying dissolution time limit of 30 minutes in Pharmaceutical equivalence studies since innovator drug product literature has recommended dissolution time of 20 minutes. Justification shall be submitted for applying "75rpm" speed for paddle apparatus for performing CDP studies, whereas innovator drug product literature has recommended speed of 50rpm.	
	3.2.P.3.3	Innovator drug product literature states as under: "To combine the low amount of empagliflozin with the relatively high quantity of metformin hydrochloride, a wet granulation process with granulation liquid containing empagliflozin was chosen." In contrast to above cited reference, applied formulation has been formulated by granulating dry mix of Metformin HCl & Empagliflozn with plain water only. Justification shall be submitted in this regard.	
	3.2.P.3.4	Unlike innovator drug product, particle size of Empagliflozin has not been identified as critical quality attribute for drug product. Justification shall be submitted in this regard.	
	3.2.P.3.5	Content uniformity test for Empagliflozin has not been included in the process validation protocol.	
	3.2.P.5.1	Justification shall be submitted for adopting dissolution time limit of 30 minutes whereas innovator drug product literature has recommended dissolution time limit of "20 minutes".	
	3.2.P.5.3	Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component".	
	3.2.P.8	Reconciliation record for the imported quantity of Empagliflozin shall be submitted against all the stability batches manufactured for different strengths and combinations.	

Decision pf 331st meeting: Registration Board deferred the cases for submission of reply to the above cited shortcomings.

Firm's reply:

Section#	Observations	Firm's response
1.6.5	Name of the drug substance manufacturer of Metformin HCl declared in section 1.6.5 is different form that declared in the submitted GMP certificate. Submit valid GMP certificate/DML of the drug substance manufacturer of Metformin HCl.	Firm has submitted revised details in section 1.6.5 along with copy of GMP Certificate (No. 23064344) dated 21-06-2023 issued by Food and Drugs Control Administration Gujrat State India valid till 20-06-2026 issued in name of Aarti Drugs Limited. UNIt-II, Plot No.211-213, Road No 02 G.I.D.C Sarigam Dist Valsad
3.2.S.4.1	Justification shall be submitted for not including test of "particle size", in the submitted drug substance specifications of Empagliflozin, as recommended by innovator literature.	Firm has submitted revised drug substance specifications including test for Particle size.
3.2.S.4.2	Drug substance analytical procedure for Empagliflozin shall be submitted from both drug substance manufacturer and M./s Aspin Pharma.	Submitted.
3.2.S4.3	Analytical method verification studies performed by M./s Aspin pharma, shall be submitted for both drug substances.	Submitted

	3.2.S.4.4	COA of the relevant batch of Empagliflozin, used for manufacturing of trial bathes shall be submitted form Drug substance manufacturer. Drug substance manufacturer has declared metformin HCl as of BP grade whereas COA of Metformin HCl submitted from M.s Aspin Pharma reveals analysis as per USP. Justification shall be submitted in this regard.	Submitted Specifications for chemical andphysical test for metformin HCl are merely identical for BP and USP. Moreover, Assay method in BP monograph is on titration method whereas USP monograph use HPLC method for Assay analysis which is more accurate and precise technique scientifically due to which USP method was selected for API testing. Additionally, AMV for Metformin HCl was performed on both Assay methods, after that we revised our specifications with claim BP/USP specification.	
	3.2.P.2.2.1	Justification shall be submitted for applying dissolution time limit of 30 minutes in Pharmaceutical equivalence studies since innovator drugproduct literature has recommended dissolution timeof 20 minutes. Justification shall be submitted for applying "75rpm" speed for paddle apparatus for performing CDP studies, whereas innovator drug product literature has recommended speed of 50rpm.	As per FDA guideline for Dissolution Testing of Immediate Release Solid Oral Dosage Forms, Approaches for Setting Dissolution Specifications for a New Chemical Entity, dissolution testing should be carried out under mild test conditions, either basket method at 50/100 rpm or paddle method at 50/75 rpm as well as for highly soluble and rapidly dissolving drug products (BCS classes 1 and 3), a single-point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less Is sufficient as a routine quality control test for batch-to-batch uniformity. On the basis of above guideline dissolution test of our product as well as innovator product performed during Pharmaceutical equivalence studies complies with following parameter i.e. 75rpm for 30 minutes for dissolution. Therefore, these parameters were finalized for testing of initial and stability batches.	
	3.2.P.3.3	Innovator drug product literature states as under: "To combine the low amount of empagliflozin with the relatively high quantity of metformin hydrochloride, a wet granulation process with granulation liquid containing empagliflozin was chosen." In contrast to above cited reference, applied formulation has been formulated by granulating dry mix of Metformin HCl & Empagliflozn with plain water only. Justification shall be submitted in this regard.	Empagin -M tablet was developed using traditional granulation method. This method resembles with the manufacturing method of a Chinese drug patent(CN104586834A). Using traditional manufacturing method, stability batches of Empagin-M were manufactured. Empagin -M tablet critical attributes like content uniformity , assay, dissolution are satisfactory and its all strengths have completed stability studies with no observation therefore this manufacturing method is satisfactory.	
	3.2.P.3.4	Unlike innovator drug product, particle size of Empagliflozin has not been identified as critical quality attribute for drug product.	As per ICH guideline Q6A, decision tree # 3 "SETTING ACCEPTANCE CRITERIA FOR DRUG SUBSTANCE	

		Justification shall be submitted in this regard.	PARTICLE SIZE DISTRIBUTION", particle size of Active Pharmaceutical Ingredients might be critical parameter when impacting dissolution profile, solubility, bioavailability, drug product process ability, content uniformity as well as product appearance. If no impact on mentioned product parameters and quality attributes, then there IS provision not to include acceptance criteria for particle size. (Decision Tree # 03 reference Attached) Moreover, aforesaid product parameters and quality attributes for Empain-M Tablet range having four different strengths with composition of Empagliflozin and Metformin as 5/1000mg, 12.5/500mg, 5/500mg and 12.5/1000mg respectively does not impacted. Therefore, particle size was not included in drug product as well as in drug substance.	
	3.2.P.3.5	Content uniformity test for Empagliflozin has not been included in the process validation protocol.	Submitted	
	3.2.P.5.1	Justification shall be submitted for adopting dissolution time limit of 30 minutes whereas innovator drug product literature has recommended dissolution time limit of "20 minutes".	As per FDA guideline for Dissolution Testing of Immediate Release Solid Oral Dosage Forms, Approaches for Setting Dissolution Specifications for a New Chemical Entity, dissolution testing should be carried out under mild test conditions, either basket method at 50/100 rpm or paddle method at 50/75 rpm as well as for highly soluble and rapidly dissolving drug products (BCS classes 1 and 3), a single-point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less Is sufficient as a routine quality control test for batch-to-batch uniformity. On the basis of above guideline dissolution test of our product as well as innovator product performed during Pharmaceutical equivalence studies complies with following parameter i.e. 75rpm for 30 minutes for dissolution. Therefore, these parameters were finalized for testing of initial and stability batches.	
	3.2.P.5.3	Justification shall be submitted that how the "specificity" of the applied method has been inferred withoutthe performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component".	Specificity has been performed and no peak interference has been observec on define parameters. However, peak purity test had been conducted on Force degradation activity and found 0.990716 anc 1.0000 peak purity index for Metformin HCI and Empagliflozin respectively. This shows that analyte chromatographic peak is not attributable to any other component.	

	3.2.P.8	Reconciliation record for the imported quantity of Empagliflozin shall be submitted against all thestability batches manufactured for different strengths and combinations.	Submitted.	

Decision: Registration Board approved the applications of Empagin-M Tablet 12.5mg+1000mg, Empagin-M Tablet 12.5mg+500mg, Empagin-M Tablet 5mg+500mg, & Empagin-M Tablet 5mg+1000mg Tablet.

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

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

93.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 02-06-2022 based on inspection conducted on 18-02-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 5692 dated 01-03-2022
	Details of fee submitted	PKR 30,000/- 16301205546 dated: 15-02-2022
	The proposed proprietary name / brand name	**EmpaMet 12.5/1000mg Tablet (Empagliflozin + Metformin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Empagliflozin..... 12.5mg Metformin HCl..... 1000mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD20
	Pharmaceutical form of applied drug	White colored film coated oblong biconvex plain tablets with score line on one side.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's 14's 20's 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Synjardy** 12.5 mg/1,000 mg film-coated tablets (UK Approved)

	For generic drugs (me-too status)	**Diampa-M** Tablets 12.5mg+1000mg of M/s Getz pharma, Karachi
	Name and address of API manufacturer.	***Empagliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product **Synjardy** Tablet. Firm has submitted CDP results of their product against the innovator's product **Synjardy** Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	***Empagliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China.

	No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.		
API Lot No.	***Empagliflozin:*** 4500-201909001 Metformin HCl: MEF/19123127		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0001TAJ	T-0002TAJ	T-0003TAJ
Batch Size	3000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	02-09-2020	04-09-2020	08-09-2020
No. of Batches	03		

94.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 02-06-2022 based on inspection conducted on 18-02-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 5690 dated 01-03-2022
	Details of fee submitted	PKR 30,000/- 4265843225 dated: 15-02-2022
	The proposed proprietary name / brand name	**EmpaMet 12.5/500mg Tablet (Empagliflozin + Metformin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Empagliflozin ..... 12.5mg Metformin HCl 500mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD20

	Pharmaceutical form of applied drug	White colored film coated oblong biconvex plain tablets with score line on one side.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's 14's 20's 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Synjardy** 12.5 mg/500 mg film-coated tablets (USA Approved)
	For generic drugs (me-too status)	**XengluMet** Tablets 12.5mg+500mg of M/s Hilton pharma, Karachi
	Name and address of API manufacturer.	***Emapgliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product **XengluMet** Tablet.

		Firm has submitted CDP results of their product against the product **Xenglu** Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	***Empagliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.		
API Lot No.	***Empagliflozin:*** 4500-201909001 Metformin HCl: MEF/19123127		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0001TAK	T-0002TAK	T-0003TAK
Batch Size	3000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	13-08-2020	24-08-2020	24-08-2020
No. of Batches	03		

95.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 02-06-2022 based on inspection conducted on 18-02-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 5691 dated 01-03-2022

	Details of fee submitted	PKR 30,000/- 21363045 dated: 15-02-2022
	The proposed proprietary name / brand name	**EmpaMet 5/1000mg Tablet (Empagliflozin + Metformin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Empagliflozin ..... 5mg Metformin HCl 1000mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD20
	Pharmaceutical form of applied drug	White colored film coated oblong biconvex plain tablets with score line on one side.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's 14's 20's 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Synjardy** 5 mg/1000 mg film-coated tablets (UK Approved)
	For generic drugs (me-too status)	**XengluMet** Tablets 5mg+1000mg of M/s Hilton pharma, Karachi
	Name and address of API manufacturer.	***Empagliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product **Synjardy** Tablet. Firm has submitted CDP results of their product against the product **Synjardy** Tablet in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	***Empagliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.		
API Lot No.	***Empagliflozin:*** 4500-201909001 Metformin HCl: MEF/19123127		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0002TAD	T-0003TAD	T-0004TAD
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	01-09-2020	04-09-2020	09-09-2020
No. of Batches	03		

96.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd. Plot # 44 A & B Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 02-06-2022 based on inspection conducted on 18-02-2022.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 31-10-2016 specifying Tablet (General) section.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 5689 dated 01-03-2022
	Details of fee submitted	Rs.30,000/- dated 15-02-2022
	The proposed proprietary name / brand name	**EmpaMet 5/500mg Tablet (Empagliflozin + Metformin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Empagliflozin ..... 5mg Metformin HCl 500mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD20
	Pharmaceutical form of applied drug	White colored film coated oblong biconvex plain tablets with score line on one side.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's 14's 20's 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Synjardy** 5 mg/500 mg film-coated tablets (USA Approved)
	For generic drugs (me-too status)	**XengluMet** Tablets 5mg+500mg of M/s Hilton pharma, Karachi
	Name and address of API manufacturer.	***Empagliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China. No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

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

STABILITY STUDY DATA

Manufacturer of API	***Empagliflozin:*** Jiangsu Yongan Pharmaceutical Co., Ltd. China.No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China ***Metformin HCl:*** Aarti Drugs Ltd. India. Plot No. 211 & 213 Road 2, G.I.D.C AT & Post, Sarigam 396 155, Dist. Valsad, Gujrat State, India.		
API Lot No.	***Empagliflozin:*** 4500-201909001 Metformin HCl: MEF/19123127		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0002TAC	T-0003TAC	T-0004TAC
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	29-06-2020	29-06-2020	11-08-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Empagliflozin and Dapagliflozin Tablets, for which the inspection was conducted on 13-10-2022

		and the report was presented in 322nd meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section#	Observations	Firm's response
1.6.5	Submit valid GMP certificate/DML of the drug substance manufacturer of Metformin HCl. Submit valid GMP certificate/DML of the drug substance manufacturer of Empagliflozin, issued by the relevant regulatory authority.	Firm has submitted copy of DML no. Su 20160324 valid upto 06-12-2025 issued for M/s Jiangsu Yongan Pharmaceutical Co., Ltd. Firm has submitted License retention certificate for the period of 21-03-2019 to 0-03-2024 issued by Food & Drug Control Administration Gujarat for M.sAarti Drugs Ltd.
3.2.S.1.3	In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	This was the typo error mentioned by API manufacturer, Updated section 3.2.S.1.3 and COA is enclosed. Firm has declared as under: "Solubility is followed as per innovator and manufacturer specifcations. There wa a typographic error in solubiliy statement, which has been rectified now". Firm hassubmitted revised COA ofdrug substance.
3.2.S.4	Justification shall be submitted for declaring the solubility of Empagliflozin as "practically insoluble" in batch analysis COA from both Drug substance manufacturer and Drug product manufacturer with reference to the	Firm has submitted revised COA of Empagliflozin. British Pharmacopoeia have Potentiometric method which was already in use and verified. But then method was shifted to USP by HPLC. HPLC method verification

		Innovator drug product literature approved by US FDA & EMA. Drug substance analytical procedure for Assay test of Metformin HCl submitted by M/s Aarti Drugs, is based uponpotentiometric method whereas USP monograph recommends HPLC method for the Assay test for Metformin HCl. Drug substance analytical procedure for Assay test of Metformin HCl submitted by M/s Next pharmaceutical, is based upon HPLC method whereas analytical method verification report has been submitted for the potentiometric method.	also available but mistakenly provided the potentiometric verification.	
	3.2.S.5	COA of reference/working standard used to analyse the Empagliflozin by M/s Next Pharmaceutical shall be submitted.	Submitted	
	3.2.P.2.2.1	Pharmaceutical equivalence studies of applied formulation against the innovator/reference product shall be submitted. Justification shall be submitting for not performing CDP studies against the innovator drug product. Justification shall be submitted for applying "75rpm" speed for paddle apparatus for performing CDP studies, whereas innovator drug product literature has recommended speed of 50rpm. Submitted CDP studies for Empagliflozin in 0.1NHCl dissolution medium reveals descending results. Justification shall be submitted in this regard	Pharmaceutical equivalence and CDP studies of all strengths have been submitted, two strengths havebeen compared with Synjardy while other two strengths have been compared with Xanglumet because of unavailability of reference product. Firm has declared that it wasoverlooked that conditions for CDP are different, we will do the dissolution at 50rpm at commercial scale production. Results are decreased for bothreference and Next Pharma drug (EmpaMet 5/1000mg Tablet Verses Synjardy 5/1000mg Tablet) because in 10 minutes' drug is maximum dissolved and achieve 90.64 % for reference drug in 10 minutes so in next time points slight decrease in results observed only is due to analytical error i.e., 90.24% after 15 minutes, 89.92% after 20 minutes and 89.17% after 30 minutes which is 1.47% decrease after 30 minutes. Same in Next Pharmaceutical Product maximum dissolved and achieve 92.32 % in 10 minutes so in next time points slight decrease in results observed only is due to analytical error i.e. 91.72% after 15 minutes, 91.54% after 20 minutes	

<table>
<tr><td></td><td></td><td></td><td>and 91.19% after 30 minutes which is 1.13% decrease after 30 minutes.
•</td><td></td></tr>
<tr><td></td><td>3.2.P.3.3</td><td>Manufacturing process for the tablets of Sacubitril/valsartan is submitted instead of applied formulation.</td><td>Firm has ubmitted revised manufacturing process.</td><td></td></tr>
<tr><td></td><td>3.2.P.3.4</td><td>Unlike innovator drug product, particle size of Empagliflozin has not been identified as critical quality attribute for drug product. Justification shall be submitted in this regard.</td><td>There was no issue identified in compressibility and dissolution results and consistent results obtained during product development, so particle size was not considered.</td><td></td></tr>
<tr><td></td><td>3.2.P.5</td><td>Justification shall be submitted for adopting different dissolution parameter for Empagliflozin from that recommended by innovator drug product.
Justification shall be submitted for performing Dissolution test separately for each drug substance whereas innovator drug product literature has recommended simultaneous analysis of dissolution of both drug substances.</td><td>We followed the CDER Application No.: 206111Orig1s000 Clinical Pharmacology And Biopharmaceutics Review(S) FDA.
The reference cited by firm is no tapplicabel for applied formulation since it was for the single ingredient dryug products of Empagliflozin and Metformin while applied product is combination drug product.</td><td></td></tr>
<tr><td></td><td>3.2.P.6</td><td>COA of reference/working standard, used for analysis of drug product stability batches, shall be submitted.</td><td>Submitted.</td><td></td></tr>
<tr><td></td><td>3.2.P.8</td><td>Submit following:
Documents confirming import of drug substance, attested by DRAPI&E office.
Justification shall be submitted for significant change during accelerated stability studies of the following stability batches:
<table><tr><th>Strength</th><th>Batch#</th></tr><tr><td>Empamet 12.5mg/1000mg</td><td>T-0001TAJ</td></tr><tr><td>Empamet 12.5mg/500mg</td><td>T-0003TAK</td></tr></table></td><td>Firm has submnitted following:
Copy o fcommercial invoice no. ZY19101701G/W attested by AD I&E Lahore, dated 24-10-2019 for import of 500gm of Empagliflozin.
Copy of commercial invoice not attested by AD I&E, for 2000 Kg of Metformin HCl.
The significant change is not due todrug substance /drug formulation, because other batches also manufactured with same formulation. the variation in results is due to calculation error because weight of sample and average weight is not incorporated properly in calculations. Recalculation is attached with Raw data and calculations and there is no significant change after recalculations.</td><td></td></tr>
<tr><td></td><td colspan="2">Innovator drug product literature states as under:
“To combine the low amount of empagliflozin with the relatively high quantity of metformin hydrochloride, a wet granulation process with granulation liquid containing empagliflozin was chosen.”
In contrast to above cited reference, applied formulation has been formulated by granulating dry</td><td>Due to low quantity of Empagliflozin, Innovator add empagliflozin in granulating liquid for proper mixing of empagliflozin with metformin. We achieve this proper mixing by geometrical mixing of empagliflozin with metformin before wet granulation. With geometrical mixing, we achieve</td><td></td></tr>
</table>

	mix of Metformin HCl & Empagliflozin with binder solution. Justification shall be submitted in this regard.	the required results that are proven from content uniformity of the finished product (results mentioned in FG COA). Process sheet for geometrical mixing is also attached.	

Decision of 331st meeting: Registration Board deferred the applications of EmpaMet 12.5/1000mg Tablet, , EmpaMet 5/1000mg Tablet & EmpaMet 5/500mg Tablet for submission of dissolution testing as per innovator drug product's dissolution parameters recommended b US FDA, for all the trial batches at the next time point of long term stability studies.

Reply of Firm: Firm has submitted performance of stability studies of next time point for EmpaMet 12.5/1000mg Tablet, , EmpaMet 5/1000mg Tablet & EmpaMet 5/500mg Tablet, wherein dissolution testing has been performed as per innovator drug product's dissolution parameters recommended by US FDA

Decision: Registration Board approved the applications of EmpaMet 12.5/1000mg Tablet, EmpaMet 12.5/500mg Tablet, EmpaMet 5/1000mg Tablet & EmpaMet 5/500mg Tablet.

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

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

97.	**Name and address of manufacturer/ Applicant**	**M/s ALBRO Pharmaceuticals (Pvt) Ltd. 340-S, Industrial Estate,Kot Lakhpat,Lahore.**	
	Brand Name + Dosage Form + Strength	MEFBRO Tablet 500 mg	
	Composition	Each Tablet Contains: Mefenamic Acid……500mg	
	Diary No. Date of R & I & fee	Dy.No 12412 dated 06-03-2019 Rs.20,000/- dated 06-03-2019	
	Pharmacological Group	NSAID	
	Type of Form	Form – 5	
	Finished product Specification	Innovator Specification.	
	Pack size & Demanded Price	10's,20's,30's,14's,100's,500's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Film Coated Mefenamic Acid 500 mg tablet is approved in MHRA	
	Me-too status	Mefnac DS tablet, Efroze Karachi, Reg. No. 011270.	
	GMP status	GMP status of last three years is not available.	
	Remark of the Evaluator [XVI]	Letter was issued to firm for following deficiency: Brand Name mentioned in Form-5 is "MEFBRO" whereas challan Form and rest of documents mentioned "MEFBRA FORTE". Form-5 mentioned uncoated tablet whereas the reference regulatory authority MHRA mentioned Film coated tablets. Submit revised Form with correction as Film Coated tablet. Provide GMP inspection report	Firm has submitted revised form-5mentioning label claim as, "Each film coated Tablet contains: Mefenamic Acid...500 mg" Firm has submitted revised Productspecification as B.P along with revised master formulation of MEFBRO FORTE tablet and also submitted challan no. 365632937 dated 09-02-2022. GMP inspection dated30-05-2019 was conducted and concluded as under

		conducted within last three years. Pre-registration variation differentialfee challan. Firm mentioned innovator specification whereas monograph is present in British Pharmacopoeia.	"Based on the area inspected, people met, the documents reviewed and considering the findings of the inspection, the firm M/s Albro Pharma is complying most of the GMP guidelines under Drugs Act, 1976 and DRAP Act, 2012. However, the deficiencies pointed out were discussed with the management and the firm has agreed to submit corrective actions taken with in stipulated time period. Moreover, as per last inspection report it was maintained that the Licensing Board in its 245th Meeting held on 22-02-2016, directed the firm to purchase land of at least 4 kanals in 6 months and complete facility within a period of two years, In compliance the firm has purchased a land of 12 Kanals and 18 Marlas in District Kasur, which was approved vide DRAP, Islamabad letter No F.14/2018-Lic dated 06-03-2019. However, the firm may be asked to provide the status of new facility, so that the unit could be shifted with in stipulated time period. 4. F.I.D conducted latest inspection dated 12-08-2020 and concluded as under "In View of above findings, it was observed that the firm has rectified most of the shortcomings pointed out in previous inspections. The area of the firm is less than 04 kanal and the management informed

			that a plot has been purchased in Kasur for shifting of unit in future.
	Decision of 316th meeting: Deferred for updated status of GMP of the firm from QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.		
	Firm's reply: Firm has submitted copy of GMP certificate issued by Additional Director, DRAP Lahore issued on basis of inspection conducted on 24-07-2023.		
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
98.	Name and address of manufacturer/ Applicant	ALBRO Pharmaceuticals (Pvt) Ltd. 340-S, Industrial Estate,Kot Lakhpat,Lahore.	
	Brand Name + Dosage Form + Strength	PERIBRO Tablet 10 mg	
	Composition	Each uncoated tablet contains: Domperidone as maleate…..... 10 mg	
	Diary No. Date of R & I & fee	Dy.No 12411 dated 06-03-2019 Rs.20,000/- dated 06-03-2019	
	Pharmacological Group	Peripheral dopamine receptor antagonist	
	Type of Form	Form – 5	
	Finished product Specification	Innovators specification	
	Pack size & Demanded Price	10's,20's,30's,14's,100's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	MOTILIUM domperidone 10mg film-coated tablets TGA Approved	
	Me-too status	Domtek Tablets by M/s Stanley Pharmaceuticals (Reg#100056)	
	GMP status	GMP status of last three years is not available.	
	Remark of the Evaluator [XVI]	Letter was issued to firm for following deficiency: • Provide GMP inspection report conducted within last three years. • Pre-registration variation differential fee challan. • Firm has claimed innovator specification whereas product is present in B.P. • Firm has applied uncoated tablet whereas reference products are film coated tablets, revised formulation is required	Firm has submitted revised label claim as "film coated tablet "and finished Product specification as B.P along with revised master formulation and also submitted challan no. 8646810253 dated 09-02-2022. GMP inspection dated 30-05-2019 was conducted and concluded as under "Based on the areainspected, people met, the documents reviewed and considering the findings of the inspection, the firm M/s Albro Pharma is complying most of the GMP guidelines under Drugs Act, 1976 and DRAP Act, 2012. However, the deficiencies pointed out were discussed with the management and the firm has agreed to submit corrective actions takenwith in stipulated time period. Moreover, as per last inspection report it was maintained that the Licensing Board in its 245th Meeting held on 22-02-

			2016, directed the firm to purchase land of at least 4 kanals in 6 months and complete facility within a period of two years, In compliance the firm has purchased a land of 12 Kanals and 18 Marlas in District Kasur, which was approved vide DRAP, Islamabad letter No F.14/2018-Lic dated 06-03-2019. However, the firm may be asked to provide the status of new facility, so that the unit could be shifted with in stipulated time period. 3. F.I.D conducted latest inspection dated 12- 08-2020 and concluded as under "In View of above findings, it was observed that the firm has rectified most of the shortcomings pointed out in previous inspections. The area of the firm is less than 04 kanal and the management informed that a plot has been purchased in Kasur for shifting of unit in future.
	Decision of 316th meeting: Deferred for updated status of GMP of the firm from QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.		
	Firm's reply: Firm has submitted copy of GMP certificate issued by Additional Director, DRAP Lahore issued on basis of inspection conducted on 24-07-2023.		
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		

99.	**Name and address of manufacturer / Applicant**	**M/s Otsuka Pakistan Ltd, No. F/4-9, Hub Industrial Trading Estate, Dist; Lasbela, Balochistan.**
	Brand Name +Dosage Form + Strength	Amiparen I.V Infusion
	Diary No. Date of R& I & fee	Dy. NO. 19595 dated 31/10/2017 Fee Rs. 20,000/-
	Composition	Each 100ml contains: L-Leucince… .....1.40g L-isoleucine…..... 0.80g L-Valine… .....0.80g L-Lysine acetate…..1.48g L-Threonine…..... 0.57g L-Tryptophan… .....0.20g L-Methionine…..... 0.39g L-Phenylalanine… 0.70g L-Cysteine… .....0.10g L-Tyrosine…..... 0.05g L-Arginine…..... 1.05g L-Histidine .....0.50g L-Alanine .....0.80g Proline 0.50g

		L-Serine..... 0.30g Aminoacetic Acid…0.59g L-Aspartic Acid… 0.10g L-Glutamic acid… 0.10g Water for injection….q.s
	Pharmacological Group	Amino acid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	500ml plastic (LDPE) bottle, Rs. 575/-
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	could not be confirmed with same composition and strength.
	GMP Status	Last inspection report dated 13/12/2017, the firm is found goo and compliant as per GMP requirement.
	Remarks of the Evaluator.	The firm had initially applied for 500ml glass bottle and then the firm applied for LDPE bottle. Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume.
	Decision of 295th meeting: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in LDPE bottle with same strength, and filled volume.	
	Firm's reply: Firm has submitted following information: Amipalene infusion of M/s Otsuka Pharmaceutical Factory Sales alliance: Otsuka Pharmaceutical Co., Ltd., approved by PMDA of Japan. The reference product is available in 200ml, 300ml & 400ml bag. 高カロリー輸液用総合アミノ酸製剤 (pmda.go.jp) Firm has also submitted stability study record including summary sheets, batch manufacturing records and HPLC chromatograms.	
	Decision: Registration Board deferred the case for submission of complete stability studies data as per the checklist approved in 293rd meeting of Registration Board.	
100	Name and address of manufacturer / Applicant	M/s Otsuka Pakistan Ltd, No. F/4-9, Hub Industrial Trading Estate, Dist; Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Kidmin I.V Infusion
	Diary No. Date of R& I & fee	Dy. NO. 19596 dated 31/10/2017 Fee Rs. 20,000/-
	Composition	Each 100ml contains: L-Leucince… .....1.40g L-isoleucine…..... 0.90g L-Valine… .....1.00g L-Lysine acetate… ..0.71g L-Threonine…..... 0.35g L-Tryptophan… .....0.25g L-Methionine…..... 0.30g L-Phenylalanine… 0.50g L-Cysteine… .....0.10g L-Tyrosine…..... 0.05g L-Arginine…..... 0.45g L-Histidine .....0.35g L-Alanine .....0.25g Proline .....0.30g L-Serine..... 0.30g L-Aspartic Acid… 0.10g

		L-Glutamic acid….0.10g Water for injection….q.s
	Pharmacological Group	Amino acid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	100ml plastic (LDPE) bottle, Rs. 550/-
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed with same composition and strength.
	GMP Status	Last inspection report dated 13/12/2017, the firm is found goo and compliant as per GMP requirement.
	Remarks of the Evaluator.	Initially the product with filled volume of 200ml (which is already registered) in glass bottle was applied but now you have applied for 100ml in LDPe bottle, therefore, Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting andalready approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume. Submit requisite fee for change in the filled volume.
	Decision of 295th meeting: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in LDPE bottle with same strength, and filled volume. Submission of requisite fee for change in filled volume of the applied product.	
	Firm's reply: Firm has submitted following information: Kydomin infusion of M/s Otsuka Pharmaceutical Factory Sales alliance: Otsuka Pharmaceutical Co., Ltd., approved by PMDA of Japan. The reference product is available in 200ml & 300ml bag. 腎不全用アミノ酸製剤 (pmda.go.jp)	
	Decision: Registration Board deferred the case for submission of complete stability studies data as per the checklist approved in 293rd meeting of Registration Board.	
101.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	Macopime Injection 1 G (I.V/I.M)
	Composition	Each vial Contain: Cefepime Hcl (with Sterile L-Arginine) eq.to Cefepime…..... 1G
	Diary No. Date of R & I & fee	Dy. No 11997 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification
	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm Injection M/s Hospira, Inc. (USFDA approved)
	Me-too status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	GMP inspection report within last 3 years is required. Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. Complete method of manufacturing is required. Section approval letter of Dry Powder Injection (cephalosporin) is required.

	Previous decision of 317th meeting: Deferred for following shortcomings; GMP inspection report within last 3 years is required. Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required alongwith preregistration fee challan. Complete method of manufacturing is required. Section approval letter of Dry Powder Injection (Cephalosporin) from CLB is required**.**	
	Reply of Firm	Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P)..... 10 ml Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future. Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of Evaluator	Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. Pre-registration variation fee challan is not provided. Section approval letter of Cephalosporin from CLB is not provided.
	Decision of 321st meeting: Deferred for following shortcomings: Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing& advertising rules 1976 along with undertaking at the end of form-5. Pre-registration variation fee challan is not provided. Section approval letter from CLB is not provided	
	Firm's reply: Firm has submitted copy of letter from Secretary CLB dated 28-12-2005 for approval of Layout plan Expansion for sections including Dry powder injectable (Cephalosporin). Firm has also submitted GMP inspection report conducted by Area FID (III) dated 24-02-2022 declaring availability of Dry powder sterile injection (Cephalosporin).	
	Decision: Deferred for following as a last chance: **Form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** **Pre-registration variation fee.** **Evidence of approvcalof amnufcaturing facility i.e., Dry powder injectable (Cephalosporin) section from Central Licensig Board.**	
102.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	Macopime Injection 500 Mg (I.V/I.M)
	Composition	Each vial Contain: Cefepime HCl (with Sterile L-Arginine) eq.to Cefipime… .....500 Mg
	Diary No. Date of R & I & fee	Dy. No 11996 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification
	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Cefipime hydrochloride 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	GMP inspection report within last 3 years is required.

		Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. Complete method of manufacturing is required. Section approval letter of Dry Powder Injection (cephalosporin) is required.
	Previous decision of 317th meeting: Deferred for following shortcomings; GMP inspection report within last 3 years is required. Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required alongwith preregistration fee challan. Complete method of manufacturing is required. Section approval letter of Dry Powder Injection (Cephalosporin) from CLB is required.	
	Reply of Firm	Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P)..... 10 ml Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future. Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of Evaluator	Firm has not submitted form -5 as per prescribed formatof form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. Pre-registration variation fee challan is not provided. Section approval letter of Cephalosporin from CLB is not provided.
	Decision of 321st meeting: Deferred for following shortcomings: Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing& advertising rules 1976 along with undertaking at the end of form-5. Pre-registration variation fee challan is not provided. Section approval letter from CLB is not provided	
	Firm's reply: Firm has submitted copy of letter from Secretary CLB dated 28-12-2005 for approval of Layout plan Expansion for sections including Dry powder injectable (Cephalosporin). Firm has also submitted GMP inspection report conducted by Area FID (III) dated 24-02-2022 declaring availability of Dry powder sterile injection (Cephalosporin).	
	Decision: Deferred for following as a last chance: **Form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** **Pre-registration variation fee.** **Evidence of approvcalof amnufcaturing facility i.e, Dry powder injectable (Cephalosporin) section from Central** Licensig **Board.**	
103.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	Macopime Injection 250 Mg (I.V/I.M)
	Composition	Each vial Contain: Cefepime Hcl (with Sterile L-Arginine) eq.to Cefipime… .....250 Mg
	Diary No. Date of R & I & fee	Dy. No 11995 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification

	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Approval status of product in Reference Regulatory Authorities not confirmed.
	Me-too status	
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	GMP inspection report within last 3 years is required. Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. Complete method of manufacturing is required. Section approval letter of Dry Powder Injection (cephalosporin) is required. Approval status of product in Reference Regulatory Authorities not confirmed.
	Decision: Deferred for following shortcomings; GMP inspection report within last 3 years is required. Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required alongwith preregistration fee challan. Complete method of manufacturing is required. Section approval letter of Dry Powder Injection (Cephalosporin) from CLB is required. Evidence of approval of applied formulation in reference regulatory authorities/agencies whichwere adopted by the Registration Board in its 275th meeting.	
	Reply of Firm	Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P)..... 10 ml Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future. Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of the Evaluator	Firm has not submitted form -5 as per prescribed formatof form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. Pre-registration variation fee challan is not provided. Section approval letter of Cephalosporin from CLB is not provided. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting and me too/generic product registered in Pakistan is not provided.
	Decision of 321st meeting: Deferred for following shortcomings: Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing& advertising rules 1976 along with undertaking at the end of form-5. Pre-registration variation fee challan is not provided. Section approval letter from CLB is not provided	
	Firm's reply: Firm has submitted copy of letter from Secretary CLB dated 28-12-2005 for approval of Layout plan Expansion for sections including Dry powder injectable (Cephalosporin). Firm has also submitted GMP inspection report conducted by Area FID (III) dated 24-02-2022 declaring availability of Dry powder sterile injection (Cephalosporin).	
	Decision: Deferred for following as a last chance:	

	Form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. **Pre-registration variation fee.** **Evidence of approvcalof amnufcaturing facility i.e, Dry powder injectable (Cephalosporin) section from Central Licensig Board.**	
104.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ahad International Pharmaceuticals Ltd Dera Ismail Khan**
	Name, address of Manufacturing site.	M/s Ahad International Pharmaceuticals Ltd, 13 KM Gomal University Multan Road Dera Ismail Khan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24365 dated 03-09-2021
	Details of fee submitted	PKR 30,000/-: vide deposit slip# 4953647152
	The proposed proprietary name / brand name	**Parasafe Infusion 1gm/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml infusion contains: Paracetamol ……. 1gm
	Pharmaceutical form of applied drug	Solution for infusion
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	In house specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 10mg/ml solution for infusion (One 100ml vial contains 1000mg Acetaminophen) of M/s Accord-UK Ltd approved by MHRA of UK
	For generic drugs (me-too status)	Provas Infusion 1Gm/100ml by Sami Pharma
	GMP status of the Finished product manufacturer	Panel inspection report dated 09-07-2020 concludes satisfactory level of cGMP compliance.
	Evidence of manufacturing facility	Copy of panel inspection report dated 09-07-2020 has been submitted wherein availability of "Sterile Vial Infusion" & "Ampoule" section has been mentioned.
	Name and address of API manufacturer.	M/s Citi Pharma (Pvt) Ltd, 3KM Head Baloki Road Phool Nagar District Qasur
	Module-II (Quality3. Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Acetaminophen is present in USP and BP. The firm as submitted detail of

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Provas infusion 1Gm/100ml by Sami Pharma.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s Citi Pharma (Pvt) Ltd, 3KM Head Baloki Road Phool Nagar District Qasur		
API Lot No.	PGP20-423, PARA/AWAS-001/20-001		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 25˚C ± 2˚C / 60% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	001	002	003
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	15-09-2020	16-09-2020	17-09-2020
No. of Batches	03		

Administrative Portion

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

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.3.1	The said section declares M/s Hebei Jiheng Pharmaceutical Co. Ltd as producer of Acetaminophen instead of M/s Citi Pharma.	According to invoice Neon chemical is our indenter which deals both companies. Now we are performing all the procedure according to Hebei Jiheng Pharma.
3.2.S.4.2	Analytical procedure submitted by Drug substance manufacturer is as per USP monograph, whereas Drug product manufacturer has submitted analytical procedure as per BP monograph. Justification shall be submitted for this variation.	Drug substance manufacturer complies both BP & USP specifications. Now we adopt analytical procedure according to USP specification.
3.2.S.4.3	Clarification shall be submitted that whether submitted analytical method verification studies have been performed by M/s Citi Pharma or M/s Ahad International. Clarification shall be submitted that whether submitted analytical method verification studies have been performed as per USP or BP monograph.	Analytical method verification studies havebeen performed M/s Ahad International. Performed according ot USP monograph.
3.2.S.4.4	COA of Paracetamol submitted from M/s CITI Pharma declares it as "Analytical Working Standard", whereas results ofanalysis of relevant batch(es)of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis(CoA) of the same batch from Drug Substancemanufacturer shall be submitted. Submitted COA form M/s Citi Pharma & M/s Ahad International does not include test of sterility. Clarification shall be submitted in this regard, since the drug substance is to be used in the formulation of a sterile product.	Firim has submitted COA of drug substance from M/s Hebei Jiheng Pharmaceutical Co. Ltd. China for batch# COS012012049 which also includes sterility test.
3.2.S.4.5	The said section declares that the	Drug substance manufacturer complies both BP &

	specifications adopted are as per the monograph specified in USP while in section 3.2.S.4.2 analytical procedure as per BP monograph has been submitted.	USP specifications. Now we adopt analytical procedure according to USP specification.
3.2.P.3.5	Submitted process validation protocol mentions the strength as 1000mg/10ml whereas applied strength is 1000mg/100ml.	It is typographic mistake while the original strength is 1000mg/100ml.
3.2.P.5.1	Justification shall be submitted for the proposed pH range of 4.0 -7.0 for the drug product since the available literature of the reference product declares different pH range than that proposed by the applicant.	Actual pH range 5 – 7 for drug product according to USP specifications.
3.2.P.5.3	Performance of Linearity parameter shall be submitted in Analytical method validation studies.	Submitted.
3.2.P.5.4	The copies of complete analysis reports of all three trial batches shall be provided. Submitted analytical report of Trial-01 does not include test of Sterility & Endotoxin.	Firm has submitted copies of batch analysis reports fo all three stability bayches including results for sterility testing and endotoxin.
3.2.P.8	Submitted invoice from M/s Neon Chemicals declare quantity of Paracetamol as of 50gm. Justification shall be submitted for manufacturing of three trial batches of 400vials each with 50gm of API. Submitted stability summary sheets & reports declare condition of real time stability studies as 25˚C ± 2˚C / 60% ± 5%RH which is not as per Zone IVa. Submitted analytical record shows that Assay calculations for all three stability batches at each time point of both accelerated & long-term stability studies have been performed by applying same value of Standard peak area. Justification shall be submitted in this regard. Record of data logger of stability chambers shall besubmitted. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has submitted copy of letter from M/s Neon Chemicals, declaring submission of drug sample of 2Kg from M/s Hebei Jiheng Pharmaceutical Co., Ltd., China to M/s Ahad International. No document attested by AD I&E DRAP has been submitted in this regard. Firm has submitted revised stability summary sheets m conditions as per Zone Iva. Firm has submitted revised analytical record along with chromatograms. Record of digital data logger has beensubmitted. GMP certificate eof the drug substance manufacturer has not been submitted.

shall be submitted.

Decision of 323rd meeting: Deferred for clarification regarding manufacturer of drug substance along with documents confirming procurement of drug substance with approval of DRAP I&E office.

Firm's response: Firm has submitted documents for the procurement of Paracetamol from M/s Citi Pharma (Pvt.) Ltd., 3.5-km, head Baloki Road, Phool Nagar, Kasur-Pakistan including commercial invoice, COA of drug substance and copy of GMP certificate issued on basis of inspection conducted on 17-12-2020.

Decision of 330th meeting: Regsitration Board decided to defer the application for personal hearing of firm regarding the varied information submitted regarding the source of drug substance.

Evaluationby PEC: The form has been intimated for personal hearing.

Proceedings & Decision: Mr. Abid Khan, Director M/s Ahad International Pharmaceuticals Ltd. appeared before the Board and submitted that the documents of Chinese source for Paracetamol were submitted by mistake and they have manufactured stability batches of Paracetamol Infusion from the API procured form M/s Citi Pharma (Pvt.) Ltd., 3.5-km, head Baloki Road, Phool Nagar, Kasur-Pakistan. Mr. Abid also submitted an undertaking declaring as under:
"We the M/s Ahad International Pharmaceuticals undertake that we have not import/purchased the API (Paracetamol) from China. We have submitted the documents are true and best of our knowledge that we purchaw the API (Paracetamol) directly from M/s Citi Phamra, Kasur, Pakistan."

Registration Board while considerieng the submission from representative of M/s Ahad International Pharmaceuticals, decided to approve the application of "Parasafe Infusion 1gm/100ml" and further advised the firm to avoid such errors in future.

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

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

105.	Name, address of Applicant / 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: 05-352-0058-066904D Address: AMB HK Enterprises (Pvt) Ltd., 2nd floor, plaza 60 commercial, Bock-K, Phase-1, DHA, Lahore. Validity: 24-02-2023 Godown: N/A Status: License to sell drugs as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd., No. 18, Jinguang street, Economic &Technological Development zone, Changzhou City, Hebei Province, China. (Headd Office)
	Name, address of manufacturer(s)	M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd., No. 51, Jinguang street, Economic &Technological Development zone, Changzhou City, Hebei Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) Copy of DML No. HEBEI20150098 valid till 12/11/2025 issued by Hebei Medicla Products Administrtaion is submitted. Copy of GMP certificate no. HE20180059 valid till 16/07/2023 issued Hebei FDA.	
	Details of letter of authorization / sole agency agreement:	
	Status of the applicant	Manufacturer ☒ Importer Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP)

		Generic Drug Product (GDP)
	Intended use of 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. 30343 : 26-10-2022
	Details of fee submitted	PKR 150,000/-: 19-06-2022
	The proposed proprietary name / brand name	Movtin Injection 1g IV Powder for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Creatine Phosphate Sodium Injection……1g
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	ATC: C01EB06 other drugs used in heart diseases
	Reference to Finished product specifications	In-house
	Proposed Pack size	1's
	Proposed unit price	Rs. 1200/- for 1's
	The status in reference regulatory authorities	-
	For generic drugs (me-too status)	-
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 product.
	Name, address of drug substance manufacturer	M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd., east of Jingsi street, west area of Lingang economic & technological development zone, Canghzhou, Hebei province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies have been conducted at40oC±2 RH 75%±5 for 36 months of 3 batches Accelerated stability study is conducted at 30oC±2 and 65%RH±5% for 24 months of 3 batches Batches: 20171102, 20171103, 20171104
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of

		drug product, specifications, detail of impurities analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	The firm has submitted analytical method validations/ verification studies for the drug substance as well as for the drug product including specificity, accuracy, precision, linearity, LOD / LOQ (for impurities), system suitability etc.
	Container closure system of the drug product	Low borosilicate glass vial s with Halogenated butyl rubber stopper
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies have been conducted at 30oC±2 and 65%RH±5% for 24 months of 3 batches Batch numbers: F11812091, F11812101, F11812111 Accelerated stability studies is conducted at 40oC±2 and 75%RH±5% for 6 months of 3 batches Batches: 110331, 1103311, 1104011

Evaluation by PEC:

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Sr. No.	Observations
1	Please provide evidence of approval of the applied in same strength is reference regulatory authorities as approved in 275th meeting of Registration Board.
2	Provide pharmaceutical equivalence studies for the applied product against the innovator's / reference product along with the detail of batch number, expiry, date of manufacturing, approval status if reference country etc.
3	Compatibility study of excipient with the drug substance are required.
4	Since the product is powder for injection and the detail of accompanying reconstitution diluents have not been provided. Please detail of method of administration along with the detail of all the diluents used for reconstitution along with the compatibility studies of the formulation with the diluents.
5	As per submitted dossier, the specifications for the drug product are BP while the product is not present in BP, please clarify and submit Rs. 7,500/- fee for revision of specifications as per notification number No.F.7-11/2021-B&A/DRAP dated 07-05-2021.
6	Provide product specific sole agency agreement for the applied product.
7	Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
8	Provide original, legalized and valid CoPP confirming the free sale of the applied product in exporting country and GMP status of the manufacturing facility.

Decision: of 324th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response: Firm has submitted following:

Reference of approval of applied formulation by three European countries i.e., Romania, Slovakia & Poland for the brand of Neoton. Web links of said references are as under:

Romania: https://www.anm.ro/_/_RCP/RCP_6986_10.10.14.pdf

Slovakia: https://www.sukl.sk/hlavna-stranka-1/english-version/special-pages/medical-product-detail?page_id=842&lie_id=44895

Poland: https://rejestry.ezdrowie.gov.pl/api/rpl/medicinal-products/4685/characteristic

Pharmaceutical Equivalence studies against the Neoton Injection of Alfasigma, Poland.

Compatibility studies with the reconstitution diluent.

Original Legalized Foreign Agency Agreement from M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd in name of M/s AMB HK Enterprises (Pvt) Ltd. Original Legalized COPP (No. Hebei20210501)
Decision: Registration Board deferred the case for submission of following: **Details of the countries where the drug product is being exported by the M/s Hebei Tiancheng Pharmaceutcal Co., Ltd. China.** **Regulatory Status of applied formulation in other countries.**

106.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Name, address of Manufacturing site.	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35671; dated 08/12/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No.5927268930 dated 10/08/2022.
	The proposed proprietary name / brand name	**Fusigen-G Cream.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Betamethasone as dipropionate ..... 0.5mg (0.05% w/w) Gentamicin as Sulphate ..... 1mg (0.1% w/w)
	Pharmaceutical form of applied drug	Topical Cream.
	Pharmacotherapeutic Group of (API)	Betamethasone dipropionate (Corticosteroids) Gentamicin Sulphate (Antibiotic)
	Reference to Finished product specifications	Innovator specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Mibetin 1 mg/g + 0.5 mg/g Cream, MHRA approved. One gram of cream contains 1 mg gentamicin (as 1.67 mg gentamicin sulfate) and 0.5 mg betamethasone (as 0.64 mg betamethasone dipropionate).
	For generic drugs (me-too status)	Gentanix-B Cream, Biogen pharma, Reg. No. 070201.
	GMP status of the Finished product manufacturer	Not provided.
	Evidence of section approval.	Not provided.
	Name and address of API manufacturer.	Betamethasone dipropionate; Mahima Life Sciences Pvt. Ltd., BST Road, Ganaur District Sonepat, Haryana, India.

		Copy of GMP certificate No. 12/55-2Drug1-2020/7030 dated 26-10-2020 issued by the FDA, Haryana, Panchkula valid till 12-09-2022 is submitted. Gentamicin Sulfate: Sichuan Long March PharmaceuticalCo., Ltd., No. 448 Changqing Road, Central city district, Leshan Sichuan, Province, People's Republic of China. Copy of GMP certificate No. SC20160076 issued by CFDA, dated 23-02-2017 valid till 22-02-2022 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Betamethasone Dipropionate is present in USP. Firm has submitted detail of drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (MLBDP-010221, mfg. date 02-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. Gentamicin Sulfate is present in EP/USP. Firm has submitted detail of drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (SC-GM-20220408, mfg. date 02-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Gentamicin Sulfate: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (SC-GM-20140803, SC-GM-20140901 & SG-GM-20140902) Betamethasone dipropionate: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (MLBDP150814, MLBDP-160814 & MLBDP170814). 15
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the comparator product that is Gentanix Cream manufactured by Biogen Pharma by performing quality tests (Identification, Average weight, Uniformity of dosage form & Assay).
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Betamethasone dipropionate;** Mahima Life Sciences Pvt. Ltd., BST Road, Ganaur District Sonepat, Haryana, India. **Gentamicin Sulfate:** Sichuan Long March Pharmaceutical Co., Ltd., No. 448 Changqing Road, Central city district, Leshan Sichuan, Province, People's Republic of China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	White colour cream filled in aluminum tube.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 Tubes.	500 Tubes.	500 Tubes.
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted that their manufacturing facility is newly licensed hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Betamethasone dipropionate;** Mahima Life Sciences Pvt. Ltd., BST Road, Ganaur District Sonepat, Haryana, India. Copy of GMP certificate No. 12/55-2Drug1-2020/7030 dated 26-10-2020 issued by the FDA, Haryana, Panchkula valid till 12-09-2022 is submitted. **Gentamicin Sulfate:** Sichuan Long March Pharmaceutical Co., Ltd., No. 448 Changqing Road, Central city district, Leshan Sichuan, Province, People's Republic of China. Copy of GMP certificate No. SC20160076 issued by CFDA, dated 23-02-2017 valid till 22-02-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Documents for the procurement of API with approval from DRAP for both the drug substances shall be submitted.

Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

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

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML for Biogen life sciences shall be submitted. Valid copy of GMPcertificate/last inspection report conducted within last three yearsof Biogen life sciences shall be submitted.	Firm has submitted copy of DML No. 000911 in the name of M/s Biogen Pharmaceuticals w.e.f. 13-02-2020 and also provided change of title vide letter No. F. 1-2/2019-Lic. Dated 18-03-2021 from M/s Biogen Pharmaceuticals to M/s Biogen Life Sciences. ***Not submitted.***
2.	1.3.5	Evidence of section approval letter of Biogen Life Sciences shall be submitted.	Firm has submitted copy of section approval vide letter No. F. 1-2/2019-Lic. Dated 14-02-2020 wherein they have cream general section.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted that proposed pack size is 1's.
4.	1.6.5	Valid copy of GMP certificate of both the Drug Substance manufacturer shall be submitted.	**Gentamicin Sulfate:** Firm has once again submitted the same copy of GMP certificate No. SC20160076 issued by CFDA, dated 23-02-2017 valid till 22-02-2022. *Valid copy of GMP certificate shall be submitted.* **Betamethasone dipropionate:** No GMP certificate is submitted.
5.	3.2.S.4.1	Specification of drug substance i.e. betamethasone by drug product manufacturer shall be submitted. Specification of drug substance i.e. Gentamicin Sulfate by drug product manufacturer shall be submitted.	Submitted. Submitted.
6.	3.2.S.4.2	Analytical procedures of drug substance i.e. betamethasone by drug product manufacturer shall be submitted. Analytical procedures of drug substance i.e. Gentamicin Sulfate by drug product manufacturer shall be submitted.	Firm has submitted analytical procedures for both the drug substances i.e. betamethasone dipropionate and gentamicin sulfate as per USP specifications.
7.	3.2.S.4.3	Verification studies of the drug substance i.e. betamethasone performed by drug product manufacturer shall be submitted. Verification studies of the drug substance i.e. Gentamicin Sulfate	Submitted. Submitted.

			performed by drug product manufacturer shall be submitted.		
	8.	3.2.S.4.4	Batch analysis of the drug substance i.e. betamethasone provided by the drug substance manufacturer has assay test on UV while official monograph has mentioned HPLC. Clarification shall be submitted. COA for the drug substance Gentamicin Sulfate provided by the finished product manufacturer has not performed water content, Sulfate content and optical rotation test on the drug substance. Clarification shall be submitted. COA for drug substance i.e. Gentamicin Sulfate from drug substance manufacturer is overwritten with respect to mfg. date, release date & expiration date. Justification shall be submitted for this overwriting of COA.	*No justification submitted.* Firm has submitted new COA from both the drug substance manufacturer and drug product manufacturer for gentamicin sulfate (B. No. SC-GM-20200202, mfg. date 08-02-2020). *However, the batch No. and manufacturing date of the submitted COA are different from initially submittedCOA. No justification is submitted by the firm against this point.*	
	9.	3.2.S.4.5	Details and COA of the working standard of both the drug substances shall be submitted.	Firm has only submitted COA of the working standard for Betamethasone dipropionate. *No details and COA of the working standard for gentamicin sulfate is provided.*	
	10.	3.2.S.7.3	Stability for the drug substance i.e. Gentamicin Sulfate fromconcerned manufacturer shall be submitted as the submitted one is from Long March Pharm.	*Firm has once again submitted the same stability data.*	
	11.	3.2.P.5.1	Qualitative composition of the applied formulation is different from reference product.	Firm has submitted that formulation mentioned in CTD trial base. The actual formulation is mentioned in BMR. *However, no clear justification is provided by the firm.*	
	12.	3.2.P.2.2	Justification for not performing PE against the innovator product No details of the comparator product are submitted in PE.	Firm has submitted that Gentanix cream manufactured by Biogen pharma was easily available that's why they used the same in PE. Batch No. 2374, Mfg. date 11-2021 & Exp. date 11-2023.	
	13.	3.2.P.5.3	Complete validation/verification studies of the drug product performed by the drug product manufacturer shall be submitted.	Submitted.	
	14.	3.2.P.5.4	Submitted COAs have no pH test on the finished product. Justify.	*No justification is submitted by the firm.*	
	15.	3.2.P.8	Stability data sheets shall be as per decision of 293rd meeting with inclusion of API lot numberand batch size.	Firm has submitted stability data sheets as per decision of 293rd meeting with submission of batch size and API lot number (500 tubes each & 200507FB for	

			Justify the wave length applied in the submitted chromatograms with respect to the analytical procedures. Analytical procedures have mentioned 254nm while submitted chromatograms reflects 240nm.	betamethasone dipropionate & SC-GM-20200202 for gentamicin sulfate). *However, the newly provided stability data sheets have different values than the originally submitted. Furthermore, the API lot members mentioned are also different from the batch analysis provided in original dossiers.* *No justification submitted against this point.*	
	16.		Documents for the procurement of API with approval from DRAP for both the drug substances shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted copy of commercial invoice No. M/21-22/132 dated 03-03-2021 wherein M/s Biogen Life Sciences have imported 0.020kg of betamethasone dipropionate with batch No. 2005207 FB, mfg. date 12-2020. *However, in the submitted document invoice date, Consignee/buyer name, Batch number manufacturing date etc. all are over written and changed from original ones. Furthermore, DRAP attested clearance is not provided for the same.* Copy of commercial invoice No. 21584234 dated 12-24-2021 mentioning 0.5kg quantity of gentamicin Sulfate, batch No. SC-GM-20200202, mfg. date 02-08-2020 is submitted. *Similar to the above mentioned document, this document is also over written and no clearance certificate from DRAP is submitted.* *Not submitted.* *Submitted.*	
	17.	3.2.R	Blank master production document /batch manufacturing record to be used during the commercial manufacturing of the applied product along with copies of executed BMRs shall be submitted.	Submitted.	

Decision of 326 meeting of Registration Board: Deferred for following;

Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences.

Valid copy of GMP certificate of both the Drug Substance manufacturer shall be submitted.

Justification for the batch analysis of the drug substance i.e. betamethasone shall be submitted as drug substance manufacturer has assay test on UV while official monograph has mentioned HPLC.

Justification shall be submitted regarding the batch number and manufacturing date of the COA submitted initially and COA submitted in replies as both are different from each other.

Details and COA of the working standard i.e. Gentamicin sulfate drug substances shall be submitted.

Justification shall be submitted for difference in qualitative composition of the applied formulation from innovator product.

Pharmaceutical equivalence against the innovator product shall be submitted.

- Justification shall be submitted regarding the change in results of tests in stability data sheets that were initially submitted and that submitted in reply.
- Justification shall be submitted regarding the API lot number as the batch analysis has mentioned some other batch number while the newly submitted stability data sheets have some other lot number.
- Justify the wave length applied in the submitted chromatograms with respect to the analytical procedures. Analytical procedures have mentioned 254nm while submitted chromatograms reflects 240nm.
- Documents for the procurement of API with approval from DRAP for betamethasone dipropionate drug substances shall be submitted.
- Documents for the procurement of API with approval from DRAP for gentamicin Sulfate drug substances shall be submitted.

Reply Submitted by the Firm

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences.	***Not submitted.***
2.	Valid copy of GMP certificate of both the Drug Substance manufacturer shall be submitted.	Firm has submitted copy of License No. Chuan 20160171 valid till 25-10-2025 for M/s Sichuan Long March Pharmaceutical Co., Ltd., No. 448 Changqing Road, Central city district, Leshan Sichuan, Province, People's Republic of China. *However, no GMP certificate is provided for the other drug substance i.e Mahima Life Sciences Pvt. Ltd., BST Road, Ganaur District Sonepat, Haryana, India.*
3.	Justification for the batch analysis of the drug substance i.e. betamethasone shall be submitted as drug substance manufacturer has assay test on UV while official monograph has mentioned HPLC.	Firm has submitted that the raw material manufacturer has tested the raw material as per USP monograph.HPLC method given by USP 32 was employed for testing of the material. Firm has also submitted the SAPfor testing of the drug substance.
4.	Justification shall be submitted regarding the batch number and manufacturing date of the COA submitted initially and COA submitted in replies as both are different from each other.	***Not submitted.***
5.	Details and COA of the working standard i.e. Gentamicin sulfate drug substances shall be submitted.	Submitted.
6.	Justification shall be submitted for difference in qualitative composition of the applied formulation from innovator product.	Firm has submitted that most of the excipients used in the formulation are same as that of used by the innovator. Only few excipients are different from the innovator. However, the stability studies at accelerated as well as the real time condition of humidity and temperature depicts that both APIs are compatible with used excipients and the product is found physically and chemically stable.
7.	Pharmaceutical equivalence against the innovator product shall be submitted.	Firm has submitted that due to unavailability of innovator's product pharmaceutical equivalence was established against the DRAP approved competitor product. They further submitted pharmaceutical equivalence against Provate G cream, Batch No. 968, mfg. date 08-2023 manufactured by M/s Saffron pharmaceuticals.
8.	Justification shall be submitted regarding the change in results of tests in stability data sheets that were initially submitted and that submitted in reply.	Firm has submitted that during submission of reply to shortcoming letter, some chromatograms were misplaced from their proper position and mixed up, that's why the results were changed because of incorrect placement of relevant chromatograms with respect to their proper place.
9.	Justification shall be submitted regarding the API lot number as the batch analysis has mentioned some other batch number while the newly submitted stability data sheets have some other lot number.	Firm has submitted that it was a typographic mistake. The correct batch number and other information regarding the API are given in the COA of individual API and also submitted in 3.2.S.4 part of CTD.
10.	Justify the wave length applied in the submitted chromatograms with respect to the analytical procedures. Analytical procedures have mentioned	Firm has submitted that the wavelength at which the testing was performed is 240nm. The same wavelength is depicted in each and every chromatogram. However,

	254nm while submitted chromatograms reflects 240nm.	in standard analytical procedure of the drug product a typographic mistake occur i.e. instead of 240nm 245 was written. They further submitted corrected SAP.
11.	Documents for the procurement of API with approval from DRAP for betamethasone dipropionate drug substances shall be submitted.	***Not submitted.***
12.	Documents for the procurement of API with approval from DRAP for gentamicin Sulfate drug substances shall be submitted.	***Not submitted.***

Decision of 331st meeting: Deferred for following;

Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences.

Drug substance COA of relevant batches used for the manufacturing of trial batches, shall be submitted.

Documents for the procurement of API with approval from DRAP for Betamethasone dipropionate drug substances shall be submitted.

Documents for the procurement of API with approval from DRAP for Gentamicin sulfate drug substances shall be submitted.

Firm's response: Firm has submitted stability studies data of newly formulated trial batches as per following details:

Manufacturer of API	**Betamethasone dipropionate;** M/s Envee Drugs Pvt. Ltd.,Gujarat, India. **Gentamicin Sulfate:** M/s Fuan Pharmaceutical Group Yantai Justware Pharmaceutical, Shandong Province China
API Lot No.	**Betamethasone dipropionate;** EV/BD-231/20 **Gentamicin Sulfate:** 211011009
Documents for the procurement of API with approval from DRAP (in case of import).	**Betamethasone dipropionate:** Firm has submitted copy of license to import Betamethasone dipropionate (3Kg) issued by AD I&E Islamabad dated 11-12-2020. **Gentamicin Sulfate:** Firm has submitted copy of Loan letter from M/s Fynk Pharma in name of M/s Biogen Lifesciences for Gemtamicin sulfate along with clearance certificate issued in name of M.s Fynk Pharma for 32.46Kg of Gentamicin sulphate by AD I&E Lahore dated 05-07-2022.

However fee for submission of new stability studies dtata has not been submitted.

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

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

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

Case no. 02 Registration applications for local manufacturing of (Human) drugs of New DML

107.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic, dated: 08-04-2015.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Application ID & Date of submission	UEU-EGV-4HR6 dated 16-11-2023
	Details of fee submitted	Rs.30,000/- dated 03-11-2023
	The proposed proprietary name / brand name	**PREFLEM CAPSULE 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin….100mg
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Lyrica capsule of M/s Pfizer approved by US FDA
	Name and address of API manufacturer.	M/s PROGRESS LIFE SCIENCES PVT. LTD. Cabin no.5, Gala no. d-3,House no. 1414/3,, Sagar ware houseing, Angur Phata Road, Rahnal Village ,Bhiwandi, - 412302, Taluka: Bhiwandi - 15, District: Thane Z5, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence Comparative Dissolution Profile of their product against the reference product Lyrica capsule.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s PROGRESS LIFE SCIENCES PVT. LTD. Cabin no.5, Gala no. d-3,House no. 1414/3,, Sagar ware houseing, Angur Phata Road, Rahnal Village ,Bhiwandi, - 412302, Taluka: Bhiwandi - 15, District: Thane Z5, India		
API Lot No.	PPR/22010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP (Certificate No. 6109668) valid up to 02-11-2023 issued by Food and Drugs Administration Maharashtra- India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Loan letter form M.s Seraph pharma along with clearance certificate no. E-4204986527461 issued in name of M/s Seraph pharma by AD I&E Islamabad, for 50Kg of Pregabalin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
1.6.5	Valid DML/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
2.3.R.1.1	Complete batch manufacturing record of drug product stability batches shall be submitted	Submitted

	3.2.P.5.1	Firm shall submit fee of Rs. 7,500/- for pre- Submitted vide deposit slip# approval change/correction in drug product specifications, since Pharmacopoeial monograph is available while firm has applied innovator's specifications. 303642243279.
Decision: Approved with BP specifications **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
108.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic, dated: 08-04-2015.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Application ID & Date of submission	MVU-Q4E-MZBD dated 16-11-2023
	Details of fee submitted	Rs.30,000/- dated 03-11-2023
	The proposed proprietary name / brand name	**PREFLEM CAPSULE 75mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin….75mg
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Lyrica capsule of M/s Pfizer approved by US FDA
	Name and address of API manufacturer.	M/s PROGRESS LIFE SCIENCES PVT. LTD. Cabin no.5, Gala no. d-3,House no. 1414/3,, Sagar ware houseing, Angur Phata Road, Rahnal Village ,Bhiwandi, - 412302, Taluka: Bhiwandi - 15, District: Thane Z5, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence Comparative Dissolution Profile of their product against the reference product Lyrica capsule.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s PROGRESS LIFE SCIENCES PVT. LTD. Cabin no.5, Gala no. d-3,House no. 1414/3,, Sagar ware houseing, Angur Phata Road, Rahnal Village ,Bhiwandi, - 412302, Taluka: Bhiwandi - 15, District: Thane Z5, India		
API Lot No.	PPR/22010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP (Certificate No. 6109668) valid up to 02-11-2023 issued by Food and Drugs Administration Maharashtra- India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Loan letter form M.s Seraph pharma along with clearance certificate no. E-4204986527461 issued in name of M/s Seraph pharma by AD I&E Islamabad, for 50Kg of Pregabalin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
1.6.5	Valid DML/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
2.3.R.1.1	Complete batch manufacturing record of drug product stability batches shall be submitted	Submitted
3.2.P.5.1	Firm shall submit fee of Rs. 7,500/- for pre-approval change/correction in drug product specifications, since Pharmacopoeial monograph is available while firm has applied innovator's specifications.	Submitted vide deposit slip# 00283650.

Decision: Approved with BP specifications

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

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

109.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic, dated: 08-04-2015.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Application ID & Date of submission	MVU-Q4E-MZBD dated 16-11-2023
	Details of fee submitted	Rs.30,000/- dated 03-11-2023
	The proposed proprietary name / brand name	**PREFLEM CAPSULE 50mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin….50mg
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Lyrica capsule of M/s Pfizer approved by US FDA
	Name and address of API manufacturer.	M/s PROGRESS LIFE SCIENCES PVT. LTD. Cabin no.5, Gala no. d-3,House no. 1414/3,, Sagar ware houseing, Angur Phata Road, Rahnal Village ,Bhiwandi, - 412302, Taluka: Bhiwandi - 15, District: Thane Z5, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence Comparative Dissolution Profile of their product against the reference product Lyrica capsule.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	M/s PROGRESS LIFE SCIENCES PVT. LTD.	

	Cabin no.5, Gala no. d-3,House no. 1414/3,, Sagar ware houseing, Angur Phata Road, Rahnal Village ,Bhiwandi, - 412302, Taluka: Bhiwandi - 15, District: Thane Z5, India		
API Lot No.	PPR/22010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP (Certificate No. 6109668) valid up to 02-11-2023 issued by Food and Drugs Administration Maharashtra- India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Loan letter form M.s Seraph pharma along with clearance certificate no. E-4204986527461 issued in name of M/s Seraph pharma by AD I&E Islamabad, for 50Kg of Pregabalin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
1.6.5	Valid DML/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
2.3.R.1.1	Complete batch manufacturing record of drug product stability batches shall be submitted	Submitted
3.2.P.5.1	Firm shall submit fee of Rs. 7,500/- for pre-approval change/correction in drug product specifications, since Pharmacopoeial monograph is available while firm has applied innovator's specifications.	Submitted vide deposit slip# 090218981.

Decision: Approved with BP specifications

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

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

110.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic, dated: 08-04-2015.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Application ID & Date of submission	WBZ-XZV-6TUQ dated 13-11-2023
	Details of fee submitted	Rs.30,000/- dated 03-11-2023
	The proposed proprietary name / brand name	**TERBILET 1% cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Terbinafine as hydrochloride ……10mg
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Pharmaceutical form of applied drug	Topical cream
	Reference to Finished product specifications	Japanese pharmacopoeia
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil 1% cream approved by US FDA
	For generic drugs (me-too status)	Lamisil 1% cream of GSK Reg.#013210
	Name and address of API manufacturer.	M/s Tagoor Laboratories Pvt Limited, Survey No: 29, Tupakulagudem, Tallapudi, Andhra Pradesh 534341, India. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches

	(Conditions & duration of Stability studies)	of drug substance at both accelerated as well as real time conditions as per Zone IV
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence against the reference product Lamisil 1% cream.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Tagoor Laboratories Pvt Limited, Survey No: 29, Tupakulagudem, Tallapudi, Andhra Pradesh 534341, India. India		
API Lot No.	TBH-00622		
Description of Pack (Container closure system)	Collapsible aluminium tube		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	400 tubes	400 tubes	400 tubes
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License to manufacture Terbinafine issued in name of M/s Tagoor Laboratories Pvt Limited by the Govt. of Andhra Pradesh , Drug Control Administration valid till 1-03-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Loan letter form M.s Seraph pharma along with copy of License to import Terbinafine issued in name of M/s Seraph pharma by AD I&E Islamabad, dated 21-09-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A

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

Remarks of Evaluator:

Section no.	Observation	Firm's response
2.3.R.1.1	Complete batch manufacturing record of drug product stability batches shall be submitted	Submitted

Decision: Approved

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

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

111.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic, dated: 08-04-2015.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Application ID & Date of submission	XLU-ZX9-Z5JY dated 13-11-2023
	Details of fee submitted	Rs.30,000/- dated 03-11-2023
	The proposed proprietary name / brand name	**Terbilet 125mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine as hydrochloride ……125mg
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Terbin 125mg tablet of Martin Dow
	Name and address of API manufacturer.	M/s Tagoor Laboratories Pvt Limited, Survey No: 29, Tupakulagudem, Tallapudi, Andhra Pradesh 534341, India. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence & CDP studies against the Lamisil tablet.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Tagoor Laboratories Pvt Limited, Survey No: 29, Tupakulagudem, Tallapudi, Andhra Pradesh 534341, India. India		
API Lot No.	TBH-00622		
Description of Pack (Container closure system)	Collapsible aluminium tube		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

112.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan

	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Tablet Section (General), approval granted by DRAP (Central Licensing Board) vide letter No. F. 3-14/2004-Lic, dated: 08-04-2015.
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Application ID & Date of submission	8EW-U6U-R3Y3 dated 13-11-2023
	Details of fee submitted	Rs.30,000/- dated 03-11-2023
	The proposed proprietary name / brand name	**Terbilet 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine as hydrochloride ……250mg
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Terbin 250mg tablet of Martin Dow
	Name and address of API manufacturer.	M/s Tagoor Laboratories Pvt Limited, Survey No: 29, Tupakulagudem, Tallapudi, Andhra Pradesh 534341, India. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence & CDP studies against the Lamisil tablet.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Tagoor Laboratories Pvt Limited, Survey No: 29, Tupakulagudem, Tallapudi, Andhra Pradesh 534341, India. India		
API Lot No.	TBH-00622		
Description of Pack (Container closure system)	Collapsible aluminium tube		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License to manufacture Terbinafine issued in name of M/s Tagoor Laboratories Pvt Limited by the Govt. of Andhra Pradesh , Drug Control Administration valid till 1-03-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Loan letter form M.s Seraph pharma along with copy of License to import Terbinafine issued in name of M/s Seraph pharma by AD I&E Islamabad, dated 21-09-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
2.3.R.1.1	Complete batch manufacturing record of drug product stability batches shall be submitted	**Submitted**

Decision: Registration Board approved the applications of Terbilet 125mg tablet & Terbilet 250mg tablet

	Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
113.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27254 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-FLOX 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin ……. 500mg
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)
	Pharmaceutical form of applied drug	Film coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin Tablet 250mg Approved US FDA
	For generic drugs (me-too status)	Leflox tablet 500mg of M/s Getz Pharma
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data

		related to nomenclature, structure, generalproperties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Leflox Tablet 500mg manufactured by Getz Pharma Pakistan. Firm has submitted CDP results of their product against the Leflox Tablet 500mg in 3 dissolution medias. i.e., Acidic media (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.		
API Lot No.	DC-004-2009013		
Description of Pack (Container closure system)	Alu-Alu blister.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-041	TRT-042	TRT-043
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	10-2022	10-2022	10-2022
No. of Batches	03		

114.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27253 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-FLOX 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin ……. 250mg
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)
	Pharmaceutical form of applied drug	Film coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin Tablet 250mg Approved US FDA
	For generic drugs (me-too status)	Leflox tablet 250mg of M/s Getz Pharma (Reg. No. 026164)
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Leflox Tablet 250mg manufactured by Getz Pharma Pakistan. Firm has submitted CDP results of their product against the Leflox Tablet 250mg in 3 dissolution medias. i.e., Acidic media (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Economic Development Zone of Sanmen County, Zhejiang 317100, P.R. China.		
API Lot No.	DC-004-2009013		
Description of Pack (Container closure system)	Alu-Alu blister.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-038	TRT-039	TRT-040
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	26-09-2022	26-09-2022	26-09-2022
Date of Initiation	29-09-2022	29-09-2022	29-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate dated 29-07-2021 issued by Sanmen market supervision Administration people,s Republic of China valid for 5 years till 28-07-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of import invoice having batch number DC-004-2009013 and Invoice number LEV201103-L specifying 200Kg of Levofloxacin Hemihydrate attested by AD I&E DRAP dated 25-11-2020 in name of M/s Fahmir Pharma. Firm has also submitted loan letter from M/s Fahmir Pharma for 0.7 Kg of Levofloxacin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing. Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority of country of origin.	
3.2.S.3.1	Copies of the IR spectrum of drug substance, performed by M/s AGM pharmaceuticals shall be submitted.	
3.2.S.4.2	Analytical procedure from drug substance ,manufacturer shall be submitted.	
3.2.S.4.3	Clarification shall be submitted regarding the"placebo solution" used in the performance of specificity parameter in analytical method verification studies of drug substance. Submitted analytical method verification studies declare the concentration of Ciprofloxacin in performance of accuracy parameter. Justification shall be submitted in this regard.	
3.2.S.4.4	Submitted COA of drug substance from M/s AGM Pharmaceuticals is not signed.	
3.2.S.5	Submitted COA of working standard is not fromthe same drug substance manufacturer.Justification shall be submitted in this regard. Submitted CA of working standard does not declare the Assay value.	
3.2.S.7.3	Submitted stability reports shall be signed and stamped form drug substance manufacturer.	
3.2.P.2.2.1	Justification shall be submitted for not performing CDP and Pharmaceutical Equivalence studies against the innovator drug product. Summited results of CDP shall be justified against the solubility profile of Levofloxacin across the physiological pH range along with literary reference.	
3.2.P.3.5	Limits of dissolution test presented in process validation protocol are different form that recommended by USP monograph.	
3.2.P.5.4	Submitted COAs of drug product trial batches from M/s AGM Pharmaceuticals are not signed.	

	• Documents confirming import of drug substancewith approval of DRAP I&E office shall be submitted. Run time of submitted chromatograms for Assay analysis shall be justified against the recommendations of USP monograph. Raw data sheet for dissolution test performed during stability studies, shall be submitted. Complete batch ,manufacturing record for stability batches shall be submitted.	
Decision: Registration Board deferred the applications of AG-FLOX 500mg Tablet & AG-FLOX 250mg Tablet for submission of reply to above cited shortcomings.		
115.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27251 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-DOXY 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Doxycycline Hyclate equivalent to Doxycycline…..... 100mg
	Pharmacotherapeutic Group of (API)	Antibiotics (Tetracycline)
	Pharmaceutical form of applied drug	Hard Gelatin Capsules
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1x10's, 10x10's 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Doxycycline capsule 100mg M/S Zafa Pharmaceuticals Reg. No. 031290
	Name and address of API manufacturer.	Hebei Jiupeng Pharmaceutical Co., Ltd. No.396 Guangyuan West Street, Yougnian District, Handan City Hubai Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Vibramycin 100mg capsule manufactured by Pfizer Pakistan Ltd. Firm has submitted CDP results of their product against the innovator's product Vibramycin 100mg capsule in 3 dissolution medias. i.e Acidic media (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Jiupeng Pharmaceutical Co., Ltd. No.396 Guangyuan West Street, Yougnian District, Handan City Hubai Province China
API Lot No.	A201905008
Description of Pack (Container closure system)	Light yellowish powder filled in hard gelatin capsule shell no# 2 having yellow color cap and body packed in Alu-Pvc blister
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRC-035	TRC-036	TRC-037
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-06-22	06-06-22	06-06-22
Date of Initiation	08-06-22	08-06-22	08-06-22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of import invoice having batch number DC-004-2009013 and Invoice number LEV201103-L specifying 200Kg of Levofloxacin Hemihydrate attested by AD I&E DRAP dated 25-11-2020 in name of M/s Fahmir Pharma. Firm has also submitted loan letter from M/s Batala Pharma for 5 Kg of Levofloxacin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing. Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets is submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority of country of origin.	
•	Reference shall be submitted for the limits for testof optical rotation. Justification shall be submitted for not includingtest of Ethanol in drug substance specifications by M.s AGM Pharmaceuticals.	
•	Clarification shall be submitted regarding the "placebo solution" used in the performance of specificity parameter in analytical method verification studies of drug substance. Submitted COA of drug substance from M/s AGM Pharmaceuticals is not signed.	
•	Submitted COA of working standard is not from the same drug substance manufacturer. Justification shall be submitted in this regard. Submitted CA of working standard does not declare the Assay value.	
•	Justify the limits of dissolution test applied in Pharmaceutical Equivalence studies. Summited results of CDP shall be justified against the solubility profile of Levofloxacin	

	across the physiological pH range along with literary reference. • Limits of Assay test presented in process validation protocol are different form that recommended by USP monograph. Submitted process validation protocol does not include Dissolution test at any stage of sampling. • Limits of dissolution test shall be justified against the USP monograph of Doxycycline hyclate capsule. UV spectrophotometric parameter applied for dissolution test shall be justified against the USP monograph of Doxycycline hyclate capsule. Dissolution parameters applied for dissolution test shall be justified against the USP monographof Doxycycline hyclate capsule. Submitted analytical procedure for Assay testshall be justified against the USP monograph of Doxycycline hyclate capsule. • Analytical method verification studies for Assay test shall be submitted as per USP monograph ofDoxycycline hyclate capsule. • Run time of submitted chromatograms for Assayanalysis shall be justified against the recommendations of USP monograph. Raw data sheet for dissolution test performed during stability studies, shall be submitted. Complete batch ,manufacturing record for stability batches shall be submitted.	
Decision: Deferred for submission of reply to above cited shortcomings.		
116.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27252 dated 20-11-2023
	Details of fee submitted	Rs 30,000/- dated 13-11-2023
	The proposed proprietary name / brand name	**AG-CIP 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Ciprofloxacin HCl equivalent to Ciprofloxacin…….. 500mg
	Pharmacotherapeutic Group of (API)	Antibiotic (flouroquinolone)
	Pharmaceutical form of applied drug	Film coated Tablet

	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Novidate 500mg Tablet of M/s Sami Pharma (Reg.No. 011837)
	Name and address of API manufacturer.	Citi Pharma (Pvt) Ltd 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the = Novidat Tablet 500mg manufactured by Sami Pharma Pakistan. Firm has submitted CDP results of their product against the = Novidat Tablet 500mg in 3 dissolution medias. i.e Acidic media (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product including accuracy, precision, specificity etc
STABILITY STUDY DATA		

Manufacturer of API	Citi Pharma (Pvt) Ltd 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.		
API Lot No.	CPH2112137		
Description of Pack (Container closure system)	Alu-Alu blister .		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-022	TRT-023	TRT-024
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	17-12-2021	17-12-2021	17-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	--
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.31/2023-DRAP (AD-54697225495) dated 09-03-2023 issued by Drug Regulatory Authority of Pakistan valid for 3 years till 02-03-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of local invoice having batch number CPH2112137 and invoice number CP21-10721 specifying 5 Kg of Ciprofloxacin HCl
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing. Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority of country of origin.	
3.2.S.4.3	• Clarification shall be submitted regarding the "placebo solution" used in the performance of specificity parameter in analytical method verification studies of drug substance.	
	• Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product	
	Summited results of CDP shall be justified against the solubility profile of Ciprofloxacin across the physiological pH range along with literary reference.	
3.2.P.8.3	• Retention time of for Ciprofloxacin in Assay analysis shall be justified against the USP monograph.	

	Raw data sheet for dissolution test performed during stability studies, shall be submitted. Complete batch ,manufacturing record forstability batches shall be submitted.
Decision: Deferred for submission of reply to above cited shortcomings.	

Case no. 03 Registration applications for Finished drug product Import (Human)

117.	**Name, address of Applicant / Importer**	**M/s AMB HK ENTERPRISES(Pvt)Ltd, Pakistan**
	Details of Drug Sale License of importer	**License No:05-352-0058-104514D** **Address:** 2nd Floor Plaza 60, Commercial Block-K, Phase-1, DHA, Lahore **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore, **Validity:** 08-05-2028. **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	JARI Pharmaceutical Co., Ltd. 18 Zhenhua Road, Lianyungang City, People's Republic of China, 222006
	Name, address of manufacturer(s)	JARI Pharmaceutical Co., Ltd. 18 Zhenhua Road, Lianyungang City, People's Republic of China, 222006
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. JS20210115) dated 04-02-2021 issued by CCPIT for decitabine for injection 50 mg. 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 03-02-2023.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from JARI Pharmaceutical Co., Ltd. The letter specifies that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan. The authorization letter is valid till 02-02-2026.
	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. 26418: 23-09-2021

	Details of fee submitted	PKR 150,030/-: 26-05-2021
	The proposed proprietary name / brand name	**DECITA INJECTION 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Decitabine …….50mg
	Pharmaceutical form of applied drug	Lyophilized powder for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic
	Reference to Finished product specifications	In house
	Proposed Pack size	1's;AS per SRO
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	**FDA** Approved.
	For generic drugs (me-too status)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	JARI Pharmaceutical Co., Ltd. 18 Zhenhua Road, Lianyungang City, People's Republic of China, 222006
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ℃±2. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence with DACOGEN Injection of Pharmachemie B.V (Holland)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Medium Boron silicon glass tube-type ,20 mL

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data for 3 batches is for 36 months only.
Evaluation by PEC:		
Decision: Approvd as per policy of inspection of manufacturer abroad.		

Case no. 04 Registration applications of onsite inspection of stability studies data

118.	**Name and address of manufacturer / Applicant**	**M/s Pharmasol Pvt Ltd. Plot # 549, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Cinacalsol 30mg Tablets
	Composition	"Each Film Coated Tablet Contains: Cinacalcet (as HCl)……30mg"
	Diary No. Date of R& I & fee	Dy 24279, 13-12-2017, Rs 20,000/-
	Pharmacological Group	Calcimimetic
	Type of Form	Form-5
	Finished product Specifications	Innovators specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Mimcipar of M/s Genome Pharmaceutical Pvt. Ltd.
	GMP status	Last inspection dated 08-07-2019 & 25-07-2019 concluded that M/s Pharmasol, Lahore was operating at satisfactory level of GMP compliance
	Remarks of the Evaluator	**Deferred in 278th meeting: Decision Deferred for submission of stability data as per format decided in instant meeting.**

STABILITY STUDY DATA			
Drug	Cinacalcet (as HCl) 30mg Tablet		
Name of Manufacturer	M/s Pharmasol Pvt Ltd. Plot # 549, Sunder Industrial Estate, Lahore.		
Manufacturer of API	Cinacalcet HCl: M/s Fuan Pharmaceutical (Group) Co., Ltd., CHINA		
API Lot No.	L-1703190101		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3 & 6 months Real Time: 0, 3, 6, 9 & 12 months		
Batch No.	AJ001	AJ002	AJ003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	07-2019	07-2019	07-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**

COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate issued for Non-sterile Bulk Drug (Cinacalcet HCl, Rocuronium, Cefene) to M/s Fuan Pharmaceutical (Group) Co., Ltd. Valid Up to 06-03-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Copy of invoice (Invoice No. KSDS201902032, dated 28/03/2019) for 1.0 Kg of Cinacalcet HCl hasbeen submitted attested by AD (I & E) DRAP, Lahore, dated 06-05-2019.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

119.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Dexprazol Capsule 30mg
	Composition	Each capsule contains Dexlansoprazole dual delayed release pellets……30mg
	Diary No. Date of R& I & fee	Diary No: 23993, 13-12-2017, Rs: 20,000/-
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	14's, 28's / As per SRO
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed release capsules 30mg by M/s Takeda Pharmaceuticals America, Inc. (USFDA Approved)
	Me-too status	DDR capsule of M/s Macter pharma (Reg#088378)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 25-07-2019.
	Remarks of the Evaluator	
	Previous Decision	Deferred for application on form 5-D along with stability studies data as per format decided in instant meeting (M-278).
120.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Dexprazol Capsule 60mg
	Composition	Each capsule contains Dexlansoprazole dual delayed release pellets……60mg
	Diary No. Date of R& I & fee	Diary No: 23994, 13-12-2017, Rs: 20,000/-
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	14's, 28's / As per SRO
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed release capsules 30mg by M/s Takeda Pharmaceuticals America, Inc. (USFDA Approved)

	Me-too status	DDR capsule of M/s Macter pharma (Reg#088379)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 25-07-2019.
	Remarks of the Evaluator	
	Previous Decision	Deferred for application on form 5-D along with stability studies data as per format decided in instant meeting (M-278).

STABILITY STUDY DATA

Name of Manufacturer	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.		
Manufacturer of API	M/s Murli Krishna Pharma PVT. LTD., D-98, Ranjangaon MIDC, Ranjangaon, Taluka-Shirur, pune 412209 Maharashtra state, India.		
API Lot No.	PDL/DEF-1-060419B		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 months Real Time: 0, 3, 6 months		
Dexprazol 30mg Capsule			
Batch No.	IJ001	IJ002	IJ003
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	25-10-2019	25-10-2019	25-10-2019
No. of Batches	03		
Date of Submission	21-12-2020 (Dy. No. 33859)		
Dexprazol 60mg Capsule			
Batch No.	HJ001	HJ002	HJ003
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	25-10-2019	25-10-2019	25-10-2019
No. of Batches	03		
Date of Submission	21-12-2020 (Dy. No. 33858)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
Certificate of analysis of API.	The firm has submitted copy of certificate of analysis of pellets (Batch # PDL/DEF-1-060419B) as well asworking standard (Batch# WS/DEX/19/03) from pellet manufacturer.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Murli Krishna Pharma Pvt Ltd, India issued by Food and Drugs Administration, Maharashtra state, India. It is valid till 07-03-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested	Yes

respective documents like chromatograms, laboratory reports, data sheets etc.	
Documents confirming import of API etc.	The firm has submitted copy of invoice for the purchase of Dexlansoprazole pellets (batch # PDL/DEF-1-060419B, 2.5Kg), attested by Assistant Director (I & E) DRAP, Karachi dated 21-06-2019 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.

Sr. No.	Observations	Response of the firm
	The submitted copy of GMP certificate of M/s Murli Krishna Pharma Pvt Ltd, India is expired, you are required to submit updated copy of GMP issued by Food and Drugs Administration, Maharashtra state, India. It is valid till 03-04-2022.	The firm has submitted copy of GMP Certificate API certificate.
	Certificate of analysis of pellets from drug product manufacturer is required.	The firm submitted its certificate of analysis of Dexlansoprazole DDR pellets 23% and from drug substance manufacturer.
	Submit methods used for analysis of pellets from drug product manufacturer.	The firm has submitted its methods used for analysis of Dexlansoprazole pellets 23% w/w and from drug substance manufacturer.
	Drug product specification(s) including acceptance criteria and reference to specifications including tests and acceptance analytical procedure should be provided. criteria.	The firm has provided copy of drug product tests,
	Justify the dissolution limits of pellets The firm has submitted that 75% is the Q value wherein the value of Q has been set below and accordingly finished product specifications 75% after 120 min which is not are revised and Q value also specified in the recommended in any pharmacopoeia or finished product specification. guidance document of any reference regulatory authority.	

INSPECTION REPORT OF M/s PHARMASOL (PVT.) LTD, LAHORE

General Information

Name of Manufacturer	M/s Pharmasol (Pvt.) Ltd.
Physical Address	Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
DML No.	DML by way of formulation. No. 000872
Date of Inspection	04-09-2023
Purpose of Inspection	Panel inspection for verification of authenticity of stability data for purpose of registration of drugs with reference to DRAP Islamabad letter No. F.15-1/2022-PEC dated 2nd August, 2023
Name of Inspectors	Mr Muhammad Tariq, Director DTL, Lahore Ms Uzma Barkat, Deputy Director, DRAP, Islamabad
Name of firm representatives accompanying during inspection	Ms Tallat , R&D Manager Ms Saira Afzal, Regulatory Affairs Manager Mr Muhammad Naeem, R&D Analyst Mr Muhammad Shoaib, Deputy Manager, Quality Control Mr Kamal Subhani, Manager, Quality Control

Focus of Inspection

The inspection of M/s Pharmasol (Pvt.) Ltd., Lahore was conducted with reference to DRAP Islamabad letter No. F.15-1/2022-PEC dated 2nd August, 2023, for verification of authenticity of stability data of products namely Dexprazol Capsule 30mg, Dexprazol Capsule 30mg and Cinacalsol Tablet 30mg. The panel evaluated the relevant documentation and also visited the R&D facility and quality control laboratory of the company. The data of all three products was evaluated in accordance with the questionnaire provided as given below.

Details of Investigation

Product Name / Composition

Dexprazol Capsule 30mg

Each capsule contains:
Dexlansoprazole dual delayed release pellets.....30mg

Dexprazol Capsule 60mg

Each capsule contains:
Dexlansoprazole dual delayed release pellets.....60mg

S. No	Question	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	The firm had approval letter of DRAP (Ref. No. 15954/2018/DRAP-AD-III (I & E)) for import of API from M/s Murli Krishna, India. Relevant import documents like commercial invoice No. MKPPL/004/19-20, Forms 7, Form 3, goods

			declaration, COAs, airway bill and customs clearance documents were available.	
	Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	The firm has selected the API source as per their defined procedure for vendor qualification and evaluation "SOP # PPL/QC/SOP/037". The firm has developed a vendor evaluationform "FQC.043-00" but the evaluation data checklist was filled by the vendor only and no further assessment/evaluation was done by the firm. The firm was advised to do the final evaluation themselves after the principal/vendor provides the filled checklist.	
	Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	The firm had imported the working standard and impurity standards. Working standard was imported in the consignment having Dexlansoprazole dual delayed release pellets. Import documents were available.	
	Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Yes, the COAs of pellets and working standards were available. COA of pellets Batch No. PDL/DEF-1-060419B, working standard Batch No. WS/DEX/19/03, impurity 6 standard Batch No. VSLS/OS/DEX-071/23/093 and impurity 9 standard Batch No. VSLS/OS/DEX-074/23/094 was available.	
	Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, GMP certificate of the principal manufacturer was available.	
	Q.No.6	Did you use API manufacturer method of testing for testing API?	Yes, the firm used principal manufacturer's method of analysis for testing of pellets. The firm documented the method on internal SOP PPL/QC/B2/RMA/037 as well.	
	Q.No.7	Do you have stability studies reports on API?	The firm had the stability study data and reports as provided by the principal manufacturer The Stability study data of Batch Nos. PSL/DEF/1-180914, PDL/DEF-1-100117, PSL/DEF-1-100119 was checked.	
	Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes. The stability study of pellets had been performed by the principal manufacturer as per validated method and quantification of degradation product had been performed.	
	Q.No.9	Do you have method for quantifying the impurities in the API?	The firm was using principal manufacturer's validated method No. "MKPPL/RM/SPC/DXL/066" for testing of pellets. Impurity testing method of analysis was also given. But impurity testing had not been performed by the firm during method validation and initial testing of pellets. The firm informed later that Dexlansoprazole impurities 6 and 9 were not available with the principal at the time of import of pellets.	
	Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had some quantity of API pellets and impurity standards as informed by the R&D team.	

	Q.No.11	Have you used pharmaceutical grade excipients?	The pellets were directly filled in hard gelatin capsules. The firm used VCAPS Plus white capsules Size 2 (for Dexprazol Capsule 60mg) and Size 3 (for Dexprazol Capsule 30mg) from Capsugel, Thailand (A Lonza Company). COA of used capsules shells was available.	
	Q.No.12	Do you have documents confirming the import of the used excipients?	The firm has imported VCAPS Plus capsule shells Size 2 (for Dexprazol Capsule 60mg) and Size 3 (for Dexprazol Capsule 30mg) from Capsugel, Thailand (A Lonza Company), through DHL. Copy of proforma invoice dated 25-09-2019 was available.	
	Q.No.13	Do you have test reports and other records on the excipients used?	COA of VCAPS Plus capsule shells Size 2 (for Dexprazol Capsule 60mg) and Size 3 (for Dexprazol Capsule 30mg) used in the trial batches was available. The firm also tested the capsules and COA of Batch No. 35009401, having QC No. RE10-19-295-A Size 3 (for Dexprazol Capsule 30mg) and COA of Batch No. 35268271, having QC No. RE10-19-292-A Size 2 (for Dexprazol Capsule 60mg) was available.	
	Q.No.14	Do you have written and authorized protocols for the development of applied product?	Yes, written and authorized protocol for product development was available. The record PPL/RD/PD/004 (Dexprazol Capsule 30mg) and PPL/RD/PD/003 (for Dexprazol Capsule 60mg) was available.	
	Q.No.15	Have you performed Drug-excipients compatibility studies?	In case of Dexlansoprazole capsules, the hard gelatin capsule shells were considered as excipient. The drug-excipient compatibility study had been performed on the basis of physical appearance only.	
	Q.No.16	Have you performed comparative dissolution studies?	The firm had performed comparative dissolution study against Dexilant 30 mg Delayed release capsules Batch No. 507726 for Dexprazol Capsule 30mg capsules and Dexilant 60mg capsules Batch No. 504739 for Dexprazol Capsule 60mg. The comparative study had been performed in 0.1N HCl, pH 5.5 buffer and pH 7.0 buffer.	
	Q.No.17	Do you have product development (R&D) section?	The firm had established R&D department for product development purpose.	
	Q.No.18	Do you have necessary equipment's available in product development section for development of applied product?	The firm had availability of required equipment in product development section, however some equipment of Production section was utilized for product development purpose.	
	Q.No.19	Are the equipment's in product development section qualified?	Two equipment from Capsule Section of General production area i.e., Capsule Filling semi-automatic machine and blistering machine were used for product development process were qualified in the year 2020 and not at the time of product development. The qualification reports of capsule filling semi-automatic machine "PPL/QA/PQ/GEN/014R dated 21-02-2020" and Blister packing Machine	

<table>
<tr><td></td><td></td><td></td><td>“PPL/QA/PQ/GEN/012R dated 15-06-2020” were available.</td><td></td></tr>
<tr><td></td><td>Q.No.20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The Firm has defined a procedure for proper maintenance and calibration of equipment used in PD section. The Firm also defined a maintenance plan “PPL/FNG/SOP/09” onyearly basis. The maintenance plan was available, but the calibration/ requalification
plan was not available. Calibration certificates were available.</td><td></td></tr>
<tr><td></td><td>Q.No.21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>Currently there was total staff of 07 persons working in R & D department. 05 are technical personnel and 02 are supportive staff. The staff was trained on the activities being performed in R&D department. Training record of R&D officer Mohsin Raza was checked and found satisfactory.</td><td></td></tr>
<tr><td></td><td>Q.No.22</td><td>Have you manufactured three stability batches for the stability studies of applied product as required?</td><td>The firm had manufactured three trial batches for the stability studies of Dexprazol Capsule 30mg and Dexprazol Capsule 60mg</td><td></td></tr>
<tr><td></td><td>Q.No.23</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The firm had manufactured 3 trial batches having batch size of 2000 capsules. The firm calculated the batch size by considering the quantity required for in-process testing, finished product testing, and stability study testing. .</td><td></td></tr>
<tr><td></td><td>Q.No.24</td><td>Do you have complete record of production of stability batches?</td><td>The firm had record of production of three stability batches.
<table>
<tr><td colspan="3">Dexprazol Capsule 30mg</td></tr>
<tr><th>Batch No.</th><th>Mfg. Date</th><th>Exp. Date</th></tr>
<tr><td>IJ001</td><td>10-2019</td><td>10-2021</td></tr>
<tr><td>IJ002</td><td>10-2019</td><td>10-2021</td></tr>
<tr><td>IJ003</td><td>10-2019</td><td>10-2021</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Dexprazol Capsule 60mg</td></tr>
<tr><th>Batch No.</th><th>Mfg. Date</th><th>Exp. Date</th></tr>
<tr><td>HJ001</td><td>10-2019</td><td>10-2021</td></tr>
<tr><td>HJ002</td><td>10-2019</td><td>10-2021</td></tr>
<tr><td>HJ003</td><td>10-2019</td><td>10-2021</td></tr>
</table></td><td></td></tr>
<tr><td></td><td>Q.No.25</td><td>Do you have protocols for stability testing of stability batches?</td><td>Lab defined protocol Nos. PPL/RD/ST/004 dated 20-10-2019 (for Dexprazol Capsule 30mg) and PPL/RD/ST/003 (Dexprazol Capsule 60mg) for stability testing were available.</td><td></td></tr>
<tr><td></td><td>Q.No.26</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has validated the assay method of analysis as per defined. Validation protocol No. DEX-MV-20-002, dated 24-07-2020 and report No. DEX-MVR-20-002 date 03-08-2020 record was verified.
Obs. However, the impurity testing was not performed during method validation and initial stability study of the stability batches. The firm informed later that Dexlansoprazole impurities 6 and 9 were not available with the principal at the time of import of pellets.</td><td></td></tr>
</table>

	Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	The firm used method of analysis provided by the principal manufacturer of pellets. The firm had method validation study provided by the principal manufacturer. The firm had validated the method "DEX-MV-20-001" as per internal defined procedure. Method transfer protocol was not available.	
	Q.No.28	Do you have documents confirming the qualification of equipment's / instruments being used in the test and analysis of API and the finished drug?	Qualification documents for the equipment used for testing of pellets and finished product were available. All equipment was calibrated from the ISO 17025 accredited laboratory. However, the qualification of Dissolution apparatus had not been performed as per USP protocol (i.e., using Prednisone tablets) and the firm was advised to perform the same. The management informed that the process for procurement of standard tablets had been initiated. The firm later on, on 12-10-2023 submitted through email, the qualification protocol and report of the dissolution apparatus in the R&D department.	
	Q.No.29	Is your method of analysis stability indicating?	The firm had validated the method of analysis as per defined procedure for testing of stability batches. Validation record was available. However, impurity testing and forced degradation studies had not been done by the firm. The same was performed by the principal manufacturer of pellets.	
	Q.No.30	Is your HPLC software is 21CFR compliant?	The laboratory had HPLC systems of Waters company (E2695). Empower software was used for operating the system. The software is in compliance with 21 CFR Part 11. 21CFR compliance checklist from Kamstec (Waters HPLC Service Provider) was available. They had defined user login ids for all users and audit trail was active. List is attached.	
	Q.No.31	Can you show Audit Trail reports on stability studies testing?	The stability testing of stability study batches had been performed on Waters HPLC system. Audit trail is available and was verified for random stability time points in the system.	
	Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	The firm had completed 24 months stability study. Some of each batch manufactured for stability study were available that expired in 2021. The impurity standards of degradation products were also available but were expired.	
	Q.No.33	Do you have stability batches kept on stability testing?	No, 24 months stability study had been completed in November, 2021.	
	Q.No.34	Do you have valid calibration status for the equipment's used in production and analysis?	Yes. Equipment were calibrated and calibration certificates were available.	
	Q.No.35	Is proper and continuous monitoring and control are available for stability chamber?	Two stability chambers with data loggers connected with computer systems were provided in R&D laboratory. UPS was installed for uninterrupted power supply. It was advised to get the alarm system checked to get it effectively functional.	

		Complete list of stability chambers with capacity details as provided by the firm is **attached**.
Q.No.36	Can related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Valid GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-8-2022 issued by DRAP was available.

Product Name / Composition

3. Cinacalsol Tablet 30mg

Each film coated tablet contains:
Cinacalcet (as hydrochloride)…..... 30mg

S. No	Question	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	The firm imported Cinacalcet HCl from Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical, China and had permission letter from DRAP for import of raw material for stability studies Reference No. 15954/2015/DRAP AD-III (I&E) dated 10-12-2018 and invoice clearance No. 6330/2019-DRAP dated 06-05-2019. Other import documents were also available.
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	The firm selected the API manufacturer based on the GMP status of the principal and evaluation as per the firm's SOP for Vendor Qualification. Moreover, the firm was purchasing other APIs from the same principal.
Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	The firm informed that the working standard was received from the principal along with the consignment of the API. Import documents were not available. The firm also informed that impurity standards were not imported.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	COAs of the API Cinacalcet HCl and working standard were available.
Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, GMP certificate of API manufacturer was available.
Q.No.6	Did you use API manufacturer method of testing for testing API?	The firm used API manufacturer's method of testing.
Q.No.7	Do you have stability studies reports on API?	The firm had stability studies reports of API as provided by raw material manufacturer.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The API manufacturer had performed stability as per SIM method. Method validation study report was also available.

	Q.No.9	Do you have method for quantifying the impurities in the API?	The firm had testing method to quantify the impurities and related substances as provided by API manufacturer. However, Related substances and Isomer testing had not been done by the firm.	
	Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had some remaining quantity of the API.	
	Q.No.11	Have you used pharmaceutical grade excipients?	The firm had used pharmaceutical grade excipients.	
	Q.No.12	Do you have documents confirming the import of the used excipients?	The firm had used both locally purchased excipients. None of them were locally manufactured as per the available documents.	
	Q.No.13	Do you have test reports and other records on the excipients used?	The firm had certificates of analysis of the excipients used.	
	Q.No.14	Do you have written and authorized protocols for the development of applied product?	The firm had written and authorized protocol No. PPL/RD/PD/001 dated 25-7-2019 for the development Cinacalsol Tablet 30mg. Documents were verified	
	Q.No.15	Have you performed Drug-excipients compatibility studies?	The firm informed that Drug-excipient compatibility studies were not performed as the excipients were qualitatively same as mentioned in the Reference Listed Drug MIMPARA 30 (approved in MHRA). Document of Standard Product Characteristics of innovator was available.	
	Q.No.16	Have you performed comparative dissolution studies?	The firm had performed comparative dissolution studies for Cinacalsol Tablet 30mg (Batch No.: AJ001) against Mimpara 30mg tablets (Batch No: B1066858) in pH 1.2 dissolution media, pH 4.5 buffer and pH 6.8 buffer.	
	Q.No.17	Do you have product development (R&D) section?	The firm had product development (R&D) section.	
	Q.No.18	Do you have necessary equipments available in product development section for development of applied product?	Product development section had necessary equipment to develop Cinacalsol Tablet 30mg. However, the firm's team informed that the machinery in the general production section was utilized for compression, coating and blistering of these trial batches in 2019. This production section machinery was not qualified in 2019. Equipment qualification was done in 2020.	
	Q.No.19	Are the equipments in product development section qualified?	Yes, the equipment in product development section were qualified. However, the firm's team informed that the machinery in the general production section was utilized for compression, coating and blistering of these trial batches in 2019. This production section machinery was not	

			qualified in 2019. Equipment qualification was done in 2020.
	Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The Firm has defined a procedure for proper maintenance and calibration of equipment used in PD section. The Firm also defined a maintenance plan "PPL/FNG/SOP/09" on yearly basis. The maintenance plan was available, but the calibration/ requalification plan was not available. Calibration certificates were available.
	Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	Currently there was total staff of 07 persons working in R & D department. 05 were technical personnel and 02 were supportive staff. Training record of the R&D team for product development and analytical development was available. The staff was trained on the activities being performed in R&D department. Training record of R&D officer Mohsin Raza was checked and found satisfactory.
	Q.No.22	Have you manufactured three stability batches for the stability studies of applied product as required?	The firm had manufactured three trial batches for the stability studies of Cinacalsol Tablet 30mg.
	Q.No.23	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size was based on DRAP's guidelines for submission of scientifically rational lab scale data and number of samples required to conduct stability study.
	Q.No.24	Do you have complete record of production of stability batches?	The firm had record of production of three stability batches. **Batch No.** / **Mfg. Date** / **Exp. Date** AJ001 / 07-2019 / 06-2021 AJ002 / 07-2019 / 06-2021 AJ003 / 07-2019 / 06-2021
	Q.No.25	Do you have protocols for stability testing of stability batches?	Yes, stability study protocol No. PPL/RD/ST/001 dated 27-07-2019 was available.
	Q.No.26	Do you have developed and validated the method for testing of stability batches?	Finished product testing method No. PPL/RD/PTM/001 Issue date: 25-7-2019 was available and assay method validation had been done. The firm was advised to perform impurity, related substances and isomer testing also.
	Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Testing method was developed in-house as informed by the firm.
	Q.No.28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes, qualification documents were available. However, the qualification of Dissolution apparatus had not been performed as per USP protocol (i.e., using Prednisone tablets) and the firm was advised to perform the same. The management informed that the process for procurement of standard tablets had

		been initiated. The firm later on, on 12-10-2023 submitted through email, the qualification protocol and report of the dissolution apparatus in the R&D department.
Q.No.29	Is your method of analysis stability indicating?	No. It was advised to perform forced degradation studies and perform impurity, related substances and isomer testing also
Q.No.30	Is your HPLC software is 21CFR compliant?	(Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.)) The laboratory had HPLC systems of Waters company (E2695). Empower software was used for operating the system. The software is in compliance with 21 CFR Part 11. 21CFR compliance checklist from Kamstec (Waters HPLC Service Provider) was available. They had defined user login ids for all users and audit trail was active. List of HPLCs is attached.
Q.No.31	Can you show Audit Trail reports on stability studies testing?	Audit trail reports were available. The stability testing of stability study batches had been performed on Waters HPLC system. Audit trail was available and was verified for random stability time points in the system
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	Stability studies of the three batches were completed in July 2021. Some packs of stability batches were available in the R&D department.
Q.No.33	Do you have stability batches kept on stability testing?	No, the stability studies for 24 months were completed for the three trial batches in July, 2021.
Q.No.34	Do you have valid calibration status for the equipments used in production and analysis?	Yes. Equipment were calibrated and calibration certificates were available.
Q.No.35	Is proper and continuous monitoring and control are available for stability chamber?	(Number and utilized/available capacity of stability chambers shall also be reported.) Two stability chambers with data loggers connected with computer systems were provided in R&D laboratory. UPS was installed for uninterrupted power supply. It was advised to get the alarm system checked to get it effectively functional. Complete list of stability chambers with capacity details as provided by the firm is **attached**.
Q.No.36	Can related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Valid GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-8-2022 issued by DRAP was available.

CONCLUSION

Based on the documents reviewed, areas inspected and technical personnel met, and considering the findings of the inspection, the panel is of the view that stability studies were conducted by the firm M/s Pharmasol (Pvt.) Ltd., Lahore, and relevant data of the products Dexprazol Capsule 30mg, Dexprazol Capsule 60mg and Cinacalsol Tablet 30mg provided by the firm was verified as elaborated in the report above. The performance of dissolution test of Dexlansoprazole pellets in media of pH 5.5 and pH 7.0 to check dual delayed release action of the pellets was also confirmed from the available record and log books. Furthermore, in response to the query of the inspection panel regarding impurity testing, the firm has submitted a letter through email to the panel members on 12-10-2023 and other response on 26-10-2023. The response stated that "…we will perform Cinacalcet Isomer Test in Cinacalcet API and finished product before commercialization of the product." And "…we will test the Dexlansoprazole imprutities in Dexlansoprazole pellet before commercialization of the product".
Decision: Registration Board approved the applications of Dexprazol Capsule 30mg, Dexprazol Capsule 60mg and Cinacalsol Tablet 30mg. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.** **Manufacturer will perform test as per commitment.**

Case no. 05 Miscellaneous cases
Registrationof Glutathione Injection.

121.	**Name, address of Applicant / Importer**	**M/s 2 World Traders Pakistan. 55/2, Main Khayaban-e-Hafiz, DHA, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** 316 **Address:** 55/2 Main Khayaban-e-Hafiz Phase-V, DHA Karachi Pakistan **Address of Godown:** NA **Validity:** 15-03-2023 **Status:** Drug License by way of Whole Sale **Renewal:** Valid
	Name and address of marketing authorization holder (abroad) as per COPP	BIOMEDICA FOSCAMA Industria Chimico-Farmaceutica, S.p.A. Via Morolense n.87, 03013 Ferentino (FR) Italy.
	Name, address of manufacturer(s) as per COPP	BIOMEDICA FOSCAMA Industria Chimico-Farmaceutica, S.p.A. Via Morolense n.87, 03013 Ferentino (FR) Italy.
	Name of exporting country	Italy
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (N^{o}CPP/2021/756) dated 02-04-2021 issued by AIFA (Agenzia Italiana Del Farmaco) for TAD (Glutathione 600mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection. **GMP;** Firm has submitted the legalized copy of GMP certificate (No: IT/84/H/2020) which was

		valid till 31-12-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted attested copy of Import and Distribution Agreement between Biomedica Foscama and 2 World Traders Pakistan for the applied 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 27041 dated 30-09-2021
	Details of fee submitted	PKR 75,000/-:Slip # 944857553239 10-08-2021
	The proposed proprietary name / brand name	**TAD 600mg dry powder injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Glutathione as sodium …….600mg
	Pharmaceutical form of applied drug	White lyophilized powder packed in moulded clear type-3 vials along with 4ml solvent
	Pharmacotherapeutic Group of (API)	Antidote ATC Code: V03AB32
	Reference to Finished product specifications	European Pharmacopoeia
	Proposed Pack size	10 vials with 10 (4ml) solvent ampoules (WFI)
	Proposed unit price	As per pricing committee.
	The status in reference regulatory authorities	TAD **(AIFA** Approved) complies EU Pharmacopoeia.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Biomedica Foscama Industria Chimico-Farmaceutica S.P.A (Italy)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API for accelerated at 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months as well as Long term testing which is conducted at 25^{o}C ± 2^{o}C / 65% ± 5% RH. The stability study data is till 36 months at ≤ 25°C.
	Module-III Drug Product:	Firm has submitted data of drug product and solvent (WFI) separately, including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 applicable being the innovator product
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	API: Type III glass vials with chlorobutyl stoppers Aluminium oversealed Solvent: Type-I glass ampoules
	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^{o}C ±2^{o}C / 75% ± 5% RH for 6 months. The Long-term stability study data is conducted at 25^{o}C ±2^{o}C / 65% ± 5% RH for 36 months. Now the firm has submitted 18 months long term stability studies data as per Zone IVb conditions, detailed as under:

Batch#	**Initial date**	**Duration**
201007	07-2020	18 months
201008	07-2020	18 months
201009	07-2020	18 months

		Firm has claimed 36 months shelf life on basis of above submitted data.
	Details of diluent:	**Composition:** Water for injection **Container closure:** 4ml Type I glass ampoule. **Manufacturer:** BIOMEDICA FOSCAMA Industria Chimico-Farmaceutica, S.p.A. Via Morolense n.87, 03013 Ferentino (FR) Italy. **Stability data:** 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 Long-term stability study data at 30°C ±2°C / 75% ± 5% RH has been submitted for 9 months only.

Evaluation by PEC[II]:
Clinical profile of the applied product is as under:

Therapeutic indications:
Prophylaxis of neuropathy following chemotherapy treatment with cisplatin or analogue.
Pharmacotherapy category:
Antidotes, ATC code: V03AB32
Dosage:
The generally recommended daily dose of TAD in patients receiving cisplatin or analogue chemotherapy is 1.5 g / m2 (corresponding to 2.5 g) administered slowly intravenously.
Contraindications:
Hypersensitivity to the active ingredient.
Pharmaceutical description:
The drug substance is lyophilised in bulk form and then the bulk lyophilised powder is filled in glass vials.

Section#	Observation	Firm's response
1.5.2	Strength per unit is mentioned as Glutathione powder 600mg instead of Glutathione sodium.	Firm has corrected label claim without submission of fee.
1.5.6	Pharmacopoeial reference for applied product is stated as European Pharmacopeia, whereas European monograph is not available for applied product.	Firm has submitted statement from M/s Biomedica Foscama that the TAD 600mg/4ml powder and solvent for infusion state that the product is contained in packaging in compliance with European Pharmacopoeia.

3.2.P.2.6	Compatibility studies shall be performed with the diluent specified in individual label of the drug product.	Firm has submitted stability study of 8hours after reconstitutiton at 25±2ºC.
Diluent		
3.2.P.3.1	Details of the manufacturer of diluent shall be submitted.	
3.2.P.8.3	Long term stability studies data of diluent shall be submitted as per Zone Iva conditions till claimed shelf life i.e., 60 months.	Firm has submitted long term stability studies data of three batches as per Zone IVa for 18 months.

Decision of 320th meeting: Deferred for regulatory status of applied formulation in other reference regulatory authorities alongwith its indications, precautions, contra indications etc.

Frim's response:

Attached summary of product characteristics (SmPC) authorized by AIFA (Italian medicine agency) and that you can find on the official website of AIFA

Link: farmaci.agenziafarmaco.gov.it/bancadatifarmaci/farmaco?farmaco=027154

Being sold in Europe upon physician's prescription as TAD is registered in AIFA

Attached relevant section of Official Gazette of the Italian Republic in which decrees and lawsare published which are effective from date of publication

Excerpt according to MHRA Section 9: Unlicensed medicines and sub section 9.3 "ExpandedAccess/ Compassionate Use/ Named patient supply programmes – Guidance notes"

Evidence of sales in Europe are attached (Delivery note and CMR – Transport documents)

Attached Periodic safety update reports (PSUR) submitted to AIFA, according to the EuropeanUnion Reference Dates (EURD) list published on European Medicine Agency (EMA) website

3- Registration letters of TAD in countries, Kyrgyztan, O'zbekiston, Georgia, Azerbaijan, Kazakhstan, Laos, Philippines, China & Kuwait.

Proceedings & Decision of 323rd meeting: The Board was appriosed that in 291st meeting application of M/s Friends Pharma, Lahore was approved on basis of international reference of AIFA of Italy. The application was submitted on Form 5D, whereas the firm didn't submit product development and stability studies data as required by the Board for such applications. Moreover, reference was also forwarded to the pricing division for MRP fixation. The Board deliberated the matter in detail and decided as follows:

To refer the case to "Society of Oncology, Pakistan" for expert opinon regarding therapeutic use andneed of applied formulation.

To advise M/s Friends Pharma, Lahore to submit the stability studies data as per checklist approvedby Board in its 293rd meeting and case will be considered by the Board after above opinion.

Evaluation by PEC: During subsequent tprocessinig of the cse it has been identified that more than one society of oncology are existing e.g *Society* of Medical *Oncology Pakistan* (SMOP), Pakistan Society of Clinical Oncology, Surgical Oncology Society Pakistan, etc. Case is submitted from which expert opinion to be taken regarding therapeutic use and need of applied formulation.

Decision: Deferred for further deliberation.

Following case was considered in 323rd meeting of Registration Board, wherein the decisioncould not be recorded. Case is presented for re-consideration of Board.

122.	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	IBTAN 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan …… 300mg
	Diary No. Date of R& I & fee	Dy. No 13540 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blocker

	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Arbi 300mg Tablet of M/s Pharmevo Karachi (Reg.# 073770)
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator [II]:	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

Case no. III Registration applications applied on Form 5A after 07th March, 2019.

Following cases have been applied on Form 5A after the cut off date of 07th March, 2019, while these have to be applied on Form 5F. Submitted for consideration of Board please.

Sr.#	Nameof Applicant and Manufacturer.	Brand name	Composition	Type of Form, Diary No and Date of Submission, Deposited Fee and Date
123.	M/s Aster Life Sciences. 32-Babar Block, New Garden Town, Lahore By M/s Panacea Biotec Ltd. B-1, Extn./A-27,MCIE, Malthura Road, New Delhi, India	Vagacyte Tablets	Each Film Coated Tablet Contains: Valganciclovir Hcl Eq. To Valganciclovir…450mg	Form-5A Dy.No 8474 dated 14-06-2019 Rs.50,000/- dated 14-06-2019
124.	M/s Genome Pharmaceuticals Pvt Ltd. House # 166-A, Street # 9, Chaklala Scheme III, Rawalpindi By M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul,Turkey	Demrose 100mg/5ml Concentrate for Solution for injection or infusion	Each 5ml Contains: Iron Iii Hydroxide Sucrose Complex…100mg	Form-5A Dy.No 9561 dated 25-06-2019 Rs.100,000/- dated 20-06-2019
125.	M/s Genome Pharmaceuticals Pvt Ltd. House # 166-A, Street # 9, Chaklala Scheme III, Rawalpindi By M/s Idol Ilac Dolum San. Ve Tic. A.S. Davutpasa Cd. Cebealibey Sok. No:20 Topkapi/Istanbul, Turkey	Fersinol 100mg/2ml Solution	Each 2ml Contains: Iron Iii Hydroxide Polymaltose Complex Eq. To Elemental Iron…100mg	Form-5A Dy.No 9560 dated 25-06-2019 Rs.100,000/- dated 20-06-2019

126.	M/s Al-Qasim Enterprises. Flat # 4, Minhas Plaza, Second Floor, Munawar Colony, Adiala Road, Rawalpindi, Pakistan By M/s Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki, Greece	Paricalcitol Pharmathen 2mcg/ml Solution for Injection	1ml Solution For Injection Contains: Paricalcitol…2Mcg	Form-5A Dy.No 15441 dated 23-08-2019 Rs.50,000/- dated 21-08-2019
127.	M/s Al-Qasim Enterprises. Flat # 4, Minhas Plaza, Second Floor, Munawar Colony, Adiala Road, Rawalpindi, Pakistan By M/s Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki, Greece	Paricalcitol Pharmathen 5mcg/ml Solution for Injection	1ml Solution For Injection Contains: Paricalcitol…5Mcg	Form-5A Dy.No 15442 dated 23-08-2019 Rs.50,000/- dated 21-08-2019
128.	M/s Galaxy Group of Companies. Plot No. 28-C, Lane No. 09, Ittehad Commercial Phase VI, DHA, Karachi By M/s Hebei Yipin Pharmaceutical Co. Ltd. Sanxia Road, Economy Technology Area of Shijiazhuang, Hebei, 052165, China	Sevoflurane Liquid for Inhalation	Each 250ml Contains: Sevoflurane…100%	Form-5A Dy.No 26931 dated 12-12-2019 Rs.100,000/- dated 12-12-2019
129.	M/s Medi Mark Pharmaceuticals. Liaqat Chowk, Sahiwal, Pakistan By M/s Huons Co. Ltd. 100, Biovalley-ro, Jecheon-si, chungcheongbuk-do, Republic of Korea	Dubamin Injection	Each ml Contains: Dobutamine Hcl As Dobutamine…50mg	Form-5A Dy.No 30383 dated 15-01-2020 Rs.100,000/- dated 17-09-2019

Decision: Registration Board noted the fact that cut off date for submission of registration applications of Human Drugs on Fomr 5, 5D or 5A was 07th March, 2019 and thereafter the prescribed form for submission of registration applications of Human Drugs is Form 5F, as per Drugs (Licensing, Registering & Advertising) Rules, 1976. Since the above presented applications have not been submitted on prescribed Form 5F as per Drugs (Licensing, Registering & Advertising) Rules, 1976, hence Board decided to disposed off above applications.

SALATEEN WASEEM PHILIP

Deputy Director (PEC)

Item No. 01: New License / Section

New License

M/s High Cure Research Laboratories (DML # 000966) Sheikhupura Road, Lahore.

Central Licensing Board in its 289th meeting held on 23rd January 2023 approved the grant of DML # 000966 for following three (03) sections of dosag e forms.

Capsule (Cephalosporin) Section.

Oral Dry Powder for Suspension (Cephalosporin) Section.

Dry Powder for injection (Cephalosporin) Section.

130.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21201 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 600430068
	The proposed proprietary name / brand name	Hibectum Injection 1G IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperazone Sodium equivalent to Cefoperazone…..... 500 mg Salbactam Sodium equivalent to Salbactam .....500 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Sterile Powder for solution of intravenous injection
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Sulperazon ®** by Pfizer , Italy.
	For generic drugs (me-too status)	**Brand Name:** Xorbact. **Manufacturer:** M/s Highnoon
	Name and address of API manufacturer.	**Cefoperazone sodium & salbactam Sodium (1:1)** **Name:** M/s Zhuhi United Laboratories Co. Ltd. **Address:** No. 2428, Anji Road Sanzao Town Jinwan District Zhuhai Guangdong, China. **GMP Validity:** 05-12-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Xorbact **Manufactured by:** Highnoon Pakistan **Testing Parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Zhuhi United Laboratories Co. Ltd. **Address:** No. 2428, Anji Road Sanzao Town Jinwan District Zhuhai Guangdong, China.		
API Lot No.	3192203011		
Description of Pack (Container closure system)	White to off white powder filled in glass vials closed with a Type-I rubber stopper and sealed with aluminum/plastic cap.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	2000 vials	2000 vials	2000 vials
Manufacturing Date	05-02-2023	05-02-2023	05-02-2023
Date of Initiation	06-02-2023	06-02-2023	06-02-2023

No. of Batches	03

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	***Material loan from Mcolson*** **Invoice** of Mcolson # CEF220715JZ **Dated:** 15-07-2022 **Quantity:** 130kg **Clearance date:** 31-07-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit Clearance documents from DRAPfor procurement of API (mixture of ceforperazone sodium & salbactam sodium [1:1] **Lot # 3192203011)**.	Submitted
	Please submit GMP certificate of API manufacturer which should be in force till date.	Submitted
3.2.P.1	Please justify with calculation that how 550mg of Cefoperazone sodium in your formulation equivalent to Cefoperazone 500 mg. Please justify with calculation that how 550mg of Salbactam sodium in your formulation equivalent to Salbactam 500 mg.	Submitted
3.2.P.5	As per limits of water content (≤ 4%) in the specifications adopted for API supplier, the Japanese specification cannot be adopted for Finished Pharmaceutical product which have limits of water content (≤ 1%). You are therefore required to adopt the Innovator specifications approved in 329th meeting of Drug Registration Board and submit data accordingly along with prescribed fee of PKR 7500/- for change in specifications.	Innovator specification adopted PKR 7500/- Slip # 603838327

Decision: Approved.

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

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

131.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966)**

		19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21202 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 7341591134
	The proposed proprietary name / brand name	Hibectum Injection 2G IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperazone Sodium equivalent to Cefoperazone…..... 1000 mg Salbactam Sodium equivalent to Salbactam .....1000 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Sterile Powder for solution of intravenous injection
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Sulperazon ®** by Pfizer , Italy.
	For generic drugs (me-too status)	**Brand Name:** Xorbact. **Manufacturer:** M/s Highnoon
	Name and address of API manufacturer.	**Cefoperazone sodium & salbactam Sodium (1:1)** **Name:** M/s Zhuhi United Laboratories Co. Ltd. **Address:** No. 2428, Anji Road Sanzao Town Jinwan District Zhuhai Guangdong, China. **GMP Validity:** 05-12-2023
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis

		and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Xorbact **Manufactured by:** Highnoon Pakistan **Testing Parameters:** JP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s Zhuhi United Laboratories Co. Ltd. **Address:** No. 2428, Anji Road Sanzao Town Jinwan District Zhuhai Guangdong, China.		
API Lot No.	3192203011		
Description of Pack (Container closure system)	White to off white powder filled in glass vials closed with a Type-I rubber stopper and sealed with aluminum/plastic cap.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-04	Trial-05	Trial-06
Batch Size	2000 vials	2000 vials	2000 vials
Manufacturing Date	05-02-2023	05-02-2023	05-02-2023
Date of Initiation	06-02-2023	06-02-2023	06-02-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	***Material loan from Mcolson*** **Invoice** of Mcolson # CEF220715JZ **Dated:** 15-07-2022 **Quantity:** 130kg **Clearance date:** 31-07-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit Clearance documents from DRAP for procurement of API (mixture of ceforperazone sodium & salbactam sodium [1:1] **Lot # 3192203011)**.	Submitted
	Please submit GMP certificate of API manufacturer which should be in force till date.	Submitted
3.2.P.1	Please justify with calculation that how 550mg of Cefoperazone sodium in your formulation equivalent to Cefoperazone 500 mg. Please justify with calculation that how 550mg of Salbactam sodium in your formulation equivalent to Salbactam 500 mg.	Submitted
3.2.P.5	As per limits of water content (≤ 4%) in the specifications adopted for API supplier, the Japanese specification cannot be adopted for Finished Pharmaceutical product which have limits of water content (≤ 1%). You are therefore required to adopt the Innovator specifications approved in 329th meeting of Drug Registration Board and submit data accordingly along with prescribed fee of PKR 7500/- for change in specifications.	Innovator specification adopted PKR 7500/- Slip # 842831901

Decision: Approved.

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

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

132.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966)** **19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966)

		19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21199 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 57348255
	The proposed proprietary name / brand name	Hidroxil dry suspension 125mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: *(after reconstitution)* Cefadroxil as monohydrate .....125 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Powder for reconstitution for oral suspension
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's (60ml Amber PET bottle)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Biodroxil 125mg/5ml by Sandoz GMBH, Austria Listed in European Medicine Agency (EMA)
	For generic drugs (me-too status)	**Brand Name:** Duricef 125mg/5ml. **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Duricef 125mg/5ml **Manufactured by:** GSK Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	002240/22-12/010		
Description of Pack (Container closure system)	White to slightly yellow powder containing cefadroxil filled in amber glass bottle packed in a bleach board unit carton as (1 x1's).		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	06-02-2023	06-02-2023	06-02-2023
Date of Initiation	30-01-2023	30-01-2023	30-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 10kg **DN #** 1618 **Dated:** 13-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

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

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

133.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21200 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 6448398089
	The proposed proprietary name / brand name	Hidroxil dry suspension 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: *(after reconstitution)* Cefadroxil as monohydrate .....250 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied	Powder for reconstitution for oral suspension

	drug	
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's (60ml Amber PET bottle)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Duracef 250mg/5ml by JUTE DARMA, Spain. Listed in European Medicine Agency (EMA)
	For generic drugs (me-too status)	Brand Name: Duricef 250mg/5ml Manufacturer: M/s GSK Reg. # 010057
	Name and address of API manufacturer.	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Duricef 250mg/5ml **Manufactured by:** GSK Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	Name: M/s Pharmagen Limited.	

	Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	002240/22-12/010		
Description of Pack (Container closure system)	White to slightly yellow powder containing cefadroxil filled in amber glass bottle packed in a bleach board unit carton as (1 x1's).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	04-02-2023	04-02-2023	04-02-2023
Date of Initiation	05-02-2023	05-02-2023	05-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 10kg **DN #** 1618 **Dated:** 13-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

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

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

134.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer

		Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21193 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 95856741763
	The proposed proprietary name / brand name	Hidroxil Capsule 250 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Cefadroxil monohydrate equivalent to Cefadroxil..... 250 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Oral Hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Not verified**
	For generic drugs (me-too status)	**Not verified** **Brand Name:** Duricef 250 mg Capsule **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	*Not verified.* **Reference product:** Duricef 250mg Capsule **Manufactured by:** GSK Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	002240/22-12/010		
Description of Pack (Container closure system)	Hidroxil capsule contains cefadroxil 250mg per capsule. It is white or almost white powder. Filled in 1 size capsule having golden color cap and body blistered in ALU-ALU packed in standard unit carton 6's x 2 provided with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	15-02-2023	15-02-2023	15-02-2023
Date of Initiation	15-02-2023	15-02-2023	15-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 10kg **DN #** 1618 **Dated:** 13-01-2023

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.5.9	The reference of drug product approval in reference regulatory authorities is not verified. Please submit documented evidence for approval of Duricef 250 mg capsule in USFDA.	Not submitted
1.5.8	Please provide registration No. details for Duricef 250mg capsule.	Not submitted
3.2.P.5	Please provide batch #, registration #, invoice for **Duricef 250 mg capsule** used in pharmaceutical equivalence studies.	Not submitted

Decision: The Registration Board deferred the case for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

135.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21194 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 93564278388
	The proposed proprietary name / brand name	Hidroxil Capsule 500 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Cefadroxil monohydrate equivalent to Cefadroxil..... 500 mg
	Pharmacotherapeutic Group of	Cephalosporin Antibiotics

	(API)	
	Pharmaceutical form of applied drug	Oral Hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved **Duricef®** 500mg Capsule.
	For generic drugs (me-too status)	**Brand Name:** Duricef 500 mg Capsule **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Duricef 500mg Capsule **Manufactured by:** GSK Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	002240/22-12/010		
Description of Pack (Container closure system)	Hidroxil capsule contains cefadroxil 500mg per capsule. It is white or almost white powder. Filled in 0 size capsule having green color cap and body blistered in ALU-ALU packed in standard unit carton 6's x 2 provided with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	17-02-2023	17-02-2023	17-02-2023
Date of Initiation	27-02-2023	27-02-2023	27-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 10kg **DN #** 1618 **Dated:** 13-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved.

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

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

136.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966)

		19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21196 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 8915838228
	The proposed proprietary name / brand name	Hidine Capsule 250 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Cephradine .....250 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Oral Hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation (PL 51463/0113)
	For generic drugs (me-too status)	**Brand Name:** Velosef 250 mg Capsule **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Velosef 500mg Capsule **Manufactured by:** GSK Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	00203/142/2022		
Description of Pack (Container closure system)	White to almost white powder containing Cephradine filled in capsules having shell size "I" and off white body & cap in ALU-PVC blister packed in a bleach board unit carton as (2 x 6's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	13-02-2023	13-02-2023	13-02-2023
Date of Initiation	13-02-2023	13-02-2023	13-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 5kg **DN #** 1695 **Dated:** 21-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.5	Please provide the details along with documented evidence about the edition of USP pharmacopeia for analytical method of Cephradine capsule. How will you justify the analytical method of USP specifications for drug product while the monograph of Cephradine capsule has been removed from latest edition of USP pharmacopeia 2023?	We developed our formulation and make trial batches for Hidine 250 mg capsules in February 2023 and then there was available edition of Pharmacopeia was USP 2021 and analytical method of Cephradine is available in USP 2021 which is attached.

Proceedings of the case:

The Board discussed in detail about the status of drug products (FPP) with cephradine as active ingredient and applied with USP specifications available in USP21 edition or previous versions and meanwhile removal of monograph in latest edition of USP Pharmacopeia. The marketing status / prescription medicine status of drug products containing cephradine in USFDA has been discontinued *(without any safety & efficacy issues)* and this is the reason of removal of monograph from USP Pharmacopeia both for API & FPP because a USP monograph is a written document that details the quality standards needed by the USFDA.

The inaccessibility of reference standard of API cephradine USP due to removal of monograph of API from USP Pharmacopeia was also considered for the FPP adopting USP21. The Board was apprised by Observer from Pharma Bureau that USP will continue developing reference standards for API cephradine USP for the use of countries other than USFDA. The Board is also of point of view that firms can adopt API specifications from other official Pharmacopeia (BP/EP) in the light of the policy under USFDA's Document No. MAPP 5310.7 Rev. 1 effective from 13th October 2017 (https://www.fda.gov/media/72412/download) issued by Office of Pharmaceutical Quality (OPQ), which is a manual of policy and procedures regarding Acceptability of Standards from Alternative Compendia (BP/EP/JP), the policy has been explained as under.

> It is reasonable to accept an applicant's proposal to use a quality standard from theBP, EP, or JP as part of the specifications for an excipient, drug substance, or drug product in the drug application, if the standard in the BP, EP, or JP is equivalent to or better than the corresponding standard in the USP/NF. Equivalent standards have the same acceptance criteria and make use of analytical procedures based on similar principles (e.g., chromatographic, spectroscopic, titration) and performance characteristics (e.g., specificity, accuracy, precision).
>
> A standard can be considered better than a corresponding standard for a number of reasons, including narrower ranges for acceptance criteria or superior performance of the analytical procedure (e.g., improved specificity, greater accuracy).

	Although specifications (i.e., test, analytical procedure, and acceptance criteria) inthe General Chapters of the USP/NF are applicable only if there is a monograph in the USP/NF for the excipient, drug substance, or drug product being tested; these specifications may be accepted, if appropriate, in the absence of a monograph. In such cases, if the applicant proposes to use an analytical procedure from the BP, EP, or JP in lieu of the corresponding analytical procedure in the General Chapters of the USP/NF, the procedure is considered an alternative analytical procedure and may be used provided it is equivalent to or better than the corresponding analytical procedure in the USP/NF. In this circumstance, the acceptance criteria in the BP, EP, or JP monograph should be accepted only if deemed appropriate for the product under review. The Board considered the FPP with USP21*(latest and last)* testing specification that ensures that the substance is, indeed, the medicine that it claims to be.	
Decision: Approved with specifications as per USP 21st edition. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The applicant may apply as per the specification guidance document approved in 331st meeting of Registration Board.**		
137.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21197 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 223340561
	The proposed proprietary name / brand name	Hidine Capsule 500 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Cephradine .....500 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied	Oral Hard gelatin capsule

	drug	
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation (PL 51463/0114)
	For generic drugs (me-too status)	**Brand Name:** Velosef 500 mg Capsule **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Velosef 500mg Capsule **Manufactured by:** GSK Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	00203/142/2022		
Description of Pack (Container closure system)	White to almost white powder containing Cephradine filled in capsules having shell size "0" and light blue color body & cap in ALU-PVC blister packed in a bleach board unit carton as (2 x 6's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	14-02-2023	14-02-2023	14-02-2023
Date of Initiation	15-02-2023	15-02-2023	15-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 5kg **DN #** 1695 **Dated:** 21-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.5	Please provide the details along with documented evidence about the edition of USP pharmacopeia for analytical method of Cephradine capsule. How will you justify the analytical method of USP specifications for drug product while the monograph of Cephradine capsule has been removed from latest edition of USP pharmacopeia 2023?	We developed our formulation and make trial batches for Hidine 250 mg capsules in February 2023 and then there was available edition of Pharmacopeia was USP 2021 and analytical method of Cephradine is available in USP 2021 which is attached.

Proceedings of the case:

The Board discussed in detail about the status of drug products (FPP) with cephradine as active ingredient and applied with USP specifications available in USP21 edition or previous versions and meanwhile removal of monograph in latest edition of USP Pharmacopeia. The marketing status /

prescription medicine status of drug products containing cephradine in USFDA has been discontinued *(without any safety & efficacy issues)* and this is the reason of removal of monograph from USP Pharmacopeia both for API & FPP because a USP monograph is a written document that details the quality standards needed by the USFDA.

The inaccessibility of reference standard of API cephradine USP due to removal of monograph of API from USP Pharmacopeia was also considered for the FPP adopting USP21. The Board was apprised by Observer from Pharma Bureau that USP will continue developing reference standards for API cephradine USP for the use of countries other than USFDA. The Board is also of point of view that firms can adopt API specifications from other official Pharmacopeia (BP/EP) in the light of the policy under USFDA's Document No. MAPP 5310.7 Rev. 1 effective from 13th October 2017 (https://www.fda.gov/media/72412/download) issued by Office of Pharmaceutical Quality (OPQ), which is a manual of policy and procedures regarding Acceptability of Standards from Alternative Compendia (BP/EP/JP), the policy has been explained as under.

It is reasonable to accept an applicant's proposal to use a quality standard from theBP, EP, or JP as part of the specifications for an excipient, drug substance, or drug product in the drug application, if the standard in the BP, EP, or JP is equivalent to or better than the corresponding standard in the USP/NF. Equivalent standards have the same acceptance criteria and make use of analytical procedures based on similar principles (e.g., chromatographic, spectroscopic, titration) andperformance characteristics (e.g., specificity, accuracy, precision).

A standard can be considered better than a corresponding standard for a number of reasons, including narrower ranges for acceptance criteria or superior performance of the analytical procedure (e.g., improved specificity, greater accuracy).

Although specifications (i.e., test, analytical procedure, and acceptance criteria) inthe General Chapters of the USP/NF are applicable only if there is a monograph in the USP/NF for the excipient, drug substance, or drug product being tested; these specifications may be accepted, if appropriate, in the absence of a monograph.

In such cases, if the applicant proposes to use an analytical procedure from the BP, EP, or JP in lieu of the corresponding analytical procedure in the General Chapters of the USP/NF, the procedure is considered an alternative analytical procedure and may be used provided it is equivalent to or better than the corresponding analytical procedure in the USP/NF. In this circumstance, the acceptance criteria in the BP, EP, or JP monograph should be accepted only if deemed appropriate for the product under review.

The Board considered the FPP with USP21*(latest and last)* testing specification that ensures that the substance is, indeed, the medicine that it claims to be.

Decision: Approved with Specifications as per USP 21st edition.

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

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

The applicant may apply as per the specification guidance document approved in 331st meeting of Registration Board.

138.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer

		Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21195 dated 28-08-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 967949740308
	The proposed proprietary name / brand name	Hidine Dry Suspension 250mg / 5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: *(after reconstitution)* Cephradine .....250 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Oral Hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA approval year 1974. But *currently discontinued on official website of USFDA*.**
	For generic drugs (me-too status)	**Brand Name:** Velosef 250 mg / 5ml **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. GMP Validity: 17-11-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Velosef 250mg / 5ml **Manufactured by:** GSK Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Pharmagen Limited. Address: Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	00203/142/2022		
Description of Pack (Container closure system)	White to almost white powder containing Cephradine filled in capsules having shell size "0" and light blue color body & cap in ALU-PVC blister packed in a bleach board unit carton as (2 x 6's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1000 suspensions	1000 suspensions	1000 suspensions
Manufacturing Date	01-02-2023	01-02-2023	01-02-2023
Date of Initiation	01-02-2023	01-02-2023	01-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 5kg **DN #** 1695 **Dated:** 21-01-2023
4.	Data of stability batches will be supported by attested respective documents like	firm has submitted analytical record for product testing.

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

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.5.9	The status of the reference product approval in USFDA has been found ***"discontinued".*** Please submit the reference of product approval in reference regulatory authorities where it is still marketed / prescription drug.	The innovator product "Velosef" which was approved by USFDA in year 1974, is still a registered brand in Pakistan and marketed as well. Its official monograph is still available in BP pharmacopeia.
3.2.P.5	Please provide the details along with documented evidence about the edition of USP pharmacopeia for analytical method of Cephradine capsule. How will you justify the analytical method of USP specifications for drug product while the monograph of Cephradine capsule has been removed from latest edition of USP pharmacopeia2023?	We developed our formulation and make trial batches for Hidine 250 mg capsules in February 2023 and then there was available edition of Pharmacopeia was USP 2021 and analytical method of Cephradine is available in USP 2021 which is attached.

Proceedings of the case:

The Board discussed in detail about the status of drug products (FPP) with cephradine as active ingredient and applied with USP specifications available in USP21 edition or previous versions and meanwhile removal of monograph in latest edition of USP Pharmacopeia. The marketing status / prescription medicine status of drug products containing cephradine in USFDA has been discontinued *(without any safety & efficacy issues)* and this is the reason of removal of monograph from USP Pharmacopeia both for API & FPP because a USP monograph is a written document that details the quality standards needed by the USFDA.

The inaccessibility of reference standard of API cephradine USP due to removal of monograph of API from USP Pharmacopeia was also considered for the FPP adopting USP21. The Board was apprised by Observer from Pharma Bureau that USP will continue developing reference standards for API cephradine USP for the use of countries other than USFDA. The Board is also of point of view that firms can adopt API specifications from other official Pharmacopeia (BP/EP) in the light of the policy under USFDA's Document No. MAPP 5310.7 Rev. 1 effective from 13th October 2017 (https://www.fda.gov/media/72412/download) issued by Office of Pharmaceutical Quality (OPQ), which is a manual of policy and procedures regarding Acceptability of Standards from Alternative Compendia (BP/EP/JP), the policy has been explained as under.

It is reasonable to accept an applicant's proposal to use a quality standard from the BP, EP, or JP as part of the specifications for an excipient, drug substance, or drug product in the drug application, if the standard in the BP, EP, or JP is equivalent to or better than the corresponding standard in the USP/NF. Equivalent standards have the same acceptance criteria and make use of analytical procedures based on similar principles (e.g., chromatographic, spectroscopic, titration) and performance characteristics (e.g., specificity, accuracy, precision).

A standard can be considered better than a corresponding standard for a number of reasons, including narrower ranges for acceptance criteria or superior performance of the analytical procedure (e.g., improved specificity, greater accuracy).

	Although specifications (i.e., test, analytical procedure, and acceptance criteria) inthe General Chapters of the USP/NF are applicable only if there is a monograph in the USP/NF for the excipient, drug substance, or drug product being tested; these specifications may be accepted, if appropriate, in the absence of a monograph. In such cases, if the applicant proposes to use an analytical procedure from the BP, EP, or JP in lieu of the corresponding analytical procedure in the General Chapters of the USP/NF, the procedure is considered an alternative analytical procedure and may be used provided it is equivalent to or better than the corresponding analytical procedure in the USP/NF. In this circumstance, the acceptance criteria in the BP, EP, or JP monograph should be accepted only if deemed appropriate for the product under review. The Board considered the FPP with USP21*(latest and last)* testing specification that ensures that the substance is, indeed, the medicine that it claims to be.	
Decision: Approved with Specifications as per USP 21st edition. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** **The applicant may apply as per the specification guidance document approved in 331st meeting of Registration Board.**		
139.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21685 dated 01-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 8642691374
	The proposed proprietary name / brand name	Hipime Injection 250 mg IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for injection)* Cefepime HCl equivalent to Cefepime .....250 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied	Sterile powder for solution of Intravenous injection.

	drug	
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	***The information provided below by firm has not been verified from USFDA website.*** **Brand Name:** Maxipime 250 mg Injection Manufacturer: Hospira, Inc Lake Forest II, 60045, USA.
	For generic drugs (me-too status)	**Brand Name:** Cefstar **Manufacturer:** M/s Barrett Hodgson
	Name and address of API manufacturer.	**Sterile mixture of Cefepime HCl & L-arginine** **Name:** M/s Kopran Research Laboratories. **Address:** K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra, India. **GMP Validity: 19-10-2023**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** **Temperature: 40°C ± 2°C** **Humidity: 75% ± 5% RH** **Real time stability data for 36 months.** **Temperature: 25°C ± 2°C** **Humidity: 60% ± 5% RH**
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Cefstar injection 250mg **Manufactured by:** Barrett Hodgson Pakistan **Testing Parameters:** USP Specifications

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

STABILITY STUDY DATA

Manufacturer of API	**Sterile mixture of Cefepime HCl & L-arginine** **Name:** M/s Kopran Research Laboratories. **Address:** K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra, India.		
API Lot No.	CEIV/B2205067		
Description of Pack (Container closure system)	White to pale yellow powder filled in 10 ml vial and packed in a bleach board unit carton as (1 x 1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1000 packs	1000 packs	1000 Packs
Manufacturing Date	21-02-2023	21-02-2023	21-02-2023
Date of Initiation	21-02-2023	21-02-2023	21-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 70kg **Invoice #** EXP-2223-297 **Dated**: 06-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.5.9	The status of the reference product approvalin USFDA has been found ***"discontinued".*** Please submit the reference of product approval in reference regulatory authorities where it is still marketed / prescription drug.	***Firm has not submitted any valid reference for the product being marketed in any RRA countries.***
1.6.5	Please submit the GMP certificate of API manufacturer which should be inforce till date.	Firm has submitted same GMP certificate as previously submitted which was expired on 19-10-2023.

	3.2.S.7	Please submit long term stability data for mixture of cefepime HCl & L-arginine according to stability conditions of ZoneIV-A (**Temperature: 30°C ± 2°C & Humidity: 60% ± 5% RH**)	Submitted	
	3.2.P.8	Please justify that why sterility testing & bacterial endotoxins test not being part of your stability studies?	Revised stability data sheets submitted with all required information.	
		Please submit COA of API Lot # CEIV/B2205067 issued by drug substance manufacturer.	Submitted	
		Please submit evidence of DRAP clearance for procurement of API.	Submitted	

Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
The Board also directed to get clarification/explaination regarding the submission of information of Maxipime 250 mg Injection, Manufacturer: Hospira, Inc Lake Forest II, 60045, USA (not verified from the USFDA website) as reference product in its application.

140.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21686 dated 01-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 88160624
	The proposed proprietary name / brand name	Hipime Injection 500 mg IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for injection)* Cefepime HCl equivalent to Cefepime .....500 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Sterile powder for solution of Intravenous injection.
	Reference to Finished product specifications	USP Specifications

	Proposed Pack size	1 x 1's (10ml clear glass vial)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation **Brand Name:** Maxipime 500 mg Injection **Manufacturer:** Hospira, Inc Lake Forest II, 60045, USA.
	For generic drugs (me-too status)	**Brand Name:** Cefstar 500 mg **Manufacturer:** M/s Barrett Hodgson
	Name and address of API manufacturer.	**Sterile mixture of Cefepime HCl & L-arginine** **Name:** M/s Kopran Research Laboratories. **Address:** K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra, India. **GMP Validity: 19-10-2023**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** **Temperature: 40°C ± 2°C** **Humidity: 75% ± 5% RH** **Real time stability data for 36 months.** **Temperature: 25°C ± 2°C** **Humidity: 60% ± 5% RH**
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Cefstar injection 500mg **Manufactured by:** Barrett Hodgson Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	**Sterile mixture of Cefepime HCl & L-arginine** **Name:** M/s Kopran Research Laboratories. **Address:** K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra, India.		
API Lot No.	CEIV/B2205067		
Description of Pack (Container closure system)	White to pale yellow powder filled in 10 ml vial and packed in a bleach board unit carton as (1 x 1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1000 packs	1000 packs	1000 Packs
Manufacturing Date	22-02-2023	22-02-2023	22-02-2023
Date of Initiation	22-02-2023	22-02-2023	22-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not required
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 70kg **Invoice #** EXP-2223-297 **Dated**: 06-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit the GMP certificate of API manufacturer which should be inforce till date.	Firm has submitted same GMP certificate as previously submitted which was expired on 19-10-2023.
3.2.S.7	Please submit long term stability data for mixture of cefepime HCl & L-arginine according to stability conditions of Zone IV-A (**Temperature: 30°C ± 2°C & Humidity: 60% ± 5% RH**)	Submitted
3.2.P.8	Please justify that why sterility testing & bacterial endotoxins test not being part of your stability studies?	Revised stability data sheets submitted with all required information.

		Please submit COA of API Lot # CEIV/B2205067 issued by drug substance manufacturer.	Submitted	
		Please submit evidence of DRAP clearance for procurement of API.	Submitted	

Decision: Approved.

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

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

141.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s High Cure Research Laboratories (DML # 000966) 19-km, Tayyaba Industrial Zone, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21687 dated 01-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 16-08-2023 Slip # 40423751475
	The proposed proprietary name / brand name	Hipime Injection 1G IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for injection)* Cefepime HCl equivalent to Cefepime .....1000 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Pharmaceutical form of applied drug	Sterile powder for solution of Intravenous injection.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 1's (15ml clear glass vial)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation **Brand Name:** Maxipime 1000 mg Injection Manufacturer: Hospira, Inc Lake Forest II, 60045, USA.

	For generic drugs (me-too status)	**Brand Name:** Cefstar 1000 mg **Manufacturer:** M/s Barrett Hodgson
	Name and address of API manufacturer.	**<u>Sterile mixture of Cefepime HCl & L-arginine</u>** **Name:** M/s Kopran Research Laboratories. **Address:** K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra, India. **GMP Validity: 19-10-2023**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** **Temperature: 40°C ± 2°C** **Humidity: 75% ± 5% RH** **Real time stability data for 36 months.** **Temperature: 25°C ± 2°C** **Humidity: 60% ± 5% RH**
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Cefstar injection 1000mg **Manufactured by:** Barrett Hodgson Pakistan **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**<u>Sterile mixture of Cefepime HCl & L-arginine</u>** **Name:** M/s Kopran Research Laboratories. **Address:** K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra, India.
API Lot No.	CEIV/B2205067
Description of Pack (Container closure system)	White to pale yellow powder filled in 15 ml vial and packed in a bleach board unit carton as (1 x 1's)

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1000 packs	1000 packs	1000 Packs
Manufacturing Date	20-02-2023	20-02-2023	20-02-2023
Date of Initiation	20-02-2023	20-02-2023	20-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 70kg **Invoice #** EXP-2223-297 **Dated**: 06-01-2023
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit the GMP certificate of API manufacturer which should be inforce till date.	Firm has submitted same GMP certificate as previously submitted which was expired on 19-10-2023.
3.2.S.7	Please submit long term stability data for mixture of cefepime HCl & L-arginine according to stability conditions of Zone IV-A (**Temperature: 30°C ± 2°C & Humidity: 60% ± 5% RH**)	Submitted
3.2.P.8	Please justify that why sterility testing & bacterial endotoxins test not being part of your stability studies?	Revised stability data sheets submitted with all required information.
	Please submit COA of API Lot # CEIV/B2205067 issued by drug substance manufacturer.	Submitted
	Please submit evidence of DRAP clearance for procurement of API.	Submitted

Decision: Approved.

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

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

New License

M/s May & Baker (Private) Limited (DML # 000953) Multan Road, Lahore.

Central Licensing Board in its 285th meeting held on 17th & 18th March 2023 approved the grant of DML # 000953 for following five (05) sections of dosage forms.

Ampoule of sterile Liquid for Injection Section (General).
Capsule Section (General).
Oral Dry Powder Suspension Section (General).
Sachet (General) Section.
Vials of Sterile powder for injection (General)

142.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker (Private) Limited (DML # 000953) 45-km Dina Nath, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker (Private) Limited (DML # 000953) 45-km Dina Nath, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24891 dated 12-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 19-09-2023 Slip # 56472854773
	The proposed proprietary name / brand name	Maycip 125mg/5ml Dry Powder Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each reconstituted 5ml suspension contains Ciprofloxacin..... 125 mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Pharmaceutical form of applied drug	Ciprofloxacin (base) 35% taste masked Micro-pellets for reconstitution with solvent
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	15ml, 30ml, 60 ml, 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	269th meeting decision of DRB for MHRA approved formulation (125mg/2.5ml) **Brand Name:** Ciproxin 250mg/5ml (PL 00010/0211) **Manufacturer:** Bayer

	For generic drugs (me-too status)	**Brand Name:** Novidat **Manufacturer:** M/s Sami
	Name and address of API manufacturer.	**<u>Ciprofloxacin (base) 35% taste masked Micro-Pellets</u>** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad. **GMP Validity: 13-06-2024**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Novidat 125 mg/5ml **Manufactured by:** M/s Sami **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
API Lot No.	CPX1316
Description of Pack (Container closure system)	Amber colored plastic bottle packed in unit carton with plastic spoon and cup.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 06 months

	Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial - 001	Trial - 002	Trial - 003
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	12-05-2022	12-05-2022	12-05-2022
Date of Initiation	14-05-2022	14-05-2022	14-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.5.5	Please clarify the pharmacological class of active ingredient written as macrolides for Ciprofloxacin.	It was a typographical mistake which has been corrected as fluoroquinolones.
3.2.P.1	Please provide details/source & composition of the diluent for oral suspension.	Submitted Diluent: medium-chain triglycerides, sucrose, lecithin, water, and strawberry flavour.
3.2.P.2	Please justify that why Drug product performance tests *(dissolution test & deliverable volume test)* & specific tests *(microbial count test)* mentioned in USP specifications, have not been made part of your testing parameters during Pharmaceutical equivalence studies?	All test has been performed by our laboratory staff however, we have previously included results of only those parameters considered as critical tests to ensure quality of product. Now we have submitted stability sheets with results of all the tests mentioned in the monograph.
	Please justify that why comparative dissolution profile has not been performed to observe the in vitro drug release behaviour against the innovator product?	Submitted
3.2.P.8	Please justify that why Drug product performance tests *(dissolution test & deliverable volume test)* & specific tests *(microbial count test)* mentioned in USP specifications, have not been made part	All test has been performed by our laboratory staff however, we have previously included results of only those parameters considered as critical tests to ensure quality of product. Now we have submitted

		of your testing parameters during Pharmaceutical equivalence studies?	stability sheets with results of all the tests mentioned in the monograph.	

Decision: Approved.

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

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

143.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker (Private) Limited (DML # 000953) 45-km Dina Nath, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker (Private) Limited (DML # 000953) 45-km Dina Nath, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24892 dated 12-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 19-09-2023 Slip # 2699349296
	The proposed proprietary name / brand name	Maycip 250mg/5ml Dry Powder Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each reconstituted 5ml suspension contains Ciprofloxacin..... 250 mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Pharmaceutical form of applied drug	Ciprofloxacin (base) 35% taste masked Micro-pellets for reconstitution with solvent
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	15ml, 30ml, 60 ml, 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved **Brand Name:** Ciproxin 250mg/5ml (PL 00010/0211) **Manufacturer:** Bayer
	For generic drugs (me-too status)	**Brand Name:** Novidat **Manufacturer:** M/s Sami
	Name and address of API manufacturer.	**<u>Ciprofloxacin (base) 35% taste masked Micro-Pellets</u>** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.

		GMP Validity: 13-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Novidat 250 mg/5ml **Manufactured by:** M/s Sami **Testing Parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
API Lot No.	CPX1316
Description of Pack (Container closure system)	Amber colored plastic bottle packed in unit carton with plastic spoon and cup.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)

Batch No.	Trial - 001	Trial - 002	Trial - 003
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	13-05-2022	13-05-2022	13-05-2022
Date of Initiation	20-05-2022	20-05-2022	20-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.5.5	Please clarify the pharmacological classof active ingredient written as macrolides for Ciprofloxacin.	It was a typographical mistake which has been corrected as fluoroquinolones.
3.2.P.1	Please provide details/source & composition of the diluent for oral suspension.	Submitted Diluent: medium-chain triglycerides, sucrose, lecithin, water, and strawberry flavor.
3.2.P.2	Please justify that why Drug product performance tests *(dissolution test & deliverable volume test)* & specific tests *(microbial count test)* mentioned in USP specifications, have not been made part of your testing parameters during Pharmaceutical equivalence studies?	All test has been performed by our laboratory staff however, we have previously included results of only those parameters considered as critical tests to ensure quality of product. Now we have submitted stability sheets with results of all the tests mentioned in the monograph.
	Please justify that why comparative dissolution profile has not been performed to observe the in vitro drug release behaviour against the innovator product?	Submitted
3.2.P.8	Please justify that why Drug product performance tests *(dissolution test & deliverable volume test)* & specific tests *(microbial count test)* mentioned in USP specifications, have not been made part of your testing parameters during Pharmaceutical equivalence studies?	All test has been performed by our laboratory staff however, we have previously included results of only those parameters considered as critical tests to ensure quality of product. Now we have submitted stability sheets with results of all the tests mentioned in the monograph.

Decision: Approved.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
144.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker (Private) Limited** **(DML # 000953)** **45-km Dina Nath, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker (Private) Limited (DML # 000953) 45-km Dina Nath, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25269 dated 17-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 19-09-2023 Slip # 0603468181
	The proposed proprietary name / brand name	Mayzip 250 mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Azithromycin (as dihydrate)..... 250 mg
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Pharmaceutical form of applied drug	Hard gelatin capsules
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	4's, 6's, 7's, 10's, 14's,28s & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved - Rivopharm UK (PL 33155/0078)
	For generic drugs (me-too status)	**Brand Name:** Azomax 250 mg Capsule **Manufacturer:** M/s Novartis
	Name and address of API manufacturer.	**Name:** M/s Hebei Golong Pharmaceutical Co. Ltd. **Address:** 9 Xingye Street, Shijiazhuang Economic and Technological Development Zone, Hebei Province, China. **GMP Validity:** 21-10-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities,

		physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Capsule Azomax 250 mg **Manufactured by:** M/s Novartis **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Hebei Golong Pharmaceutical Co. Ltd. **Address:** 9 Xingye Street, Shijiazhuang Economic and Technological Development Zone, Hebei Province, China.		
API Lot No.	CPX1316		
Description of Pack (Container closure system)	ALU-ALU Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	Trial - 01	Trial - 02	Trial - 03

Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	08-05-2022	08-05-2022	08-05-2022
Date of Initiation	13-05-2022	13-05-2022	13-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Global Pharma **Quantity:** 100 kg **Invoice #** HBGL-2104282045 **Clearance Date:** 21-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.5.6	Please justify that why Innovator specifications have been chosen while the monograph of Capsule Azithromycin is available in pharmacopoeias.	It was a typo error USP monograph has been adopted for the testing of finished Pharmaceutical product.
3.2.P.8	Please clarify that why run time of injection in HPLC, for standards and samples, is not 1.5 times of the retention time of the peak for complete elution of the analytes?	Run time is not specifically mentioned 1.5 time as per USP monograph because no analytes are there to interfere results so we are justifying it by referring it to USP monograph. if complete elution does not occur, extra peak interferes to next chromatogram, but we don't have such phenomena in our chromatograms.
	Please clarify that why sample name/ID has been mention "**UNKNOWN**" instead of *(reference standard OR sample's batch #)* in the sample information window?	Since, the HPLC software has been set on default by the engineer of the supplier. Now we have recently make changes in SOPs for control of documentation and accordingly, the name of analyst will appear at the place of name/ID. SOP along with sample chromatogram submitted as Annex-II.
	Please submit chromatograms which should properly represent the numbers of reference standards injected, sample of drug product with batch # & dissolution samples.	Submitted

		Please submit complete stability data for the minimum 0,3,6 month interval of minimum 03 stability batches.	Submitted	

Decision: Approved.

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

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

145.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker (Private) Limited (DML # 000953) 45-km Dina Nath, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker (Private) Limited (DML # 000953) 45-km Dina Nath, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24890 dated 12-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 19-09-2023 Slip # 242826371133
	The proposed proprietary name / brand name	Panzole Sterile Dry Powder 40 mg Vial IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains (Powder for injection) Pantroprazole (as sodium sesquihydrate) …40 mg **After reconstitution:** 4mg/ml
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	Sterile powder for reconstitution
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA & EMAE approved formulation.
	For generic drugs (me-too status)	**Brand Name:** Protonix 40mg injection **Manufacturer:** M/s Wilshire
	Name and address of API manufacturer.	**36% Pantroprazole Sodium sterile *(lyophilized)*** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd.

		Address: Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad. **GMP Validity: 13-06-2024**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Protonix 40 mg injection **Manufactured by:** M/s Wilshire **Testing Parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
API Lot No.	1904901
Description of Pack (Container closure system)	10 ml glass vials with 10 ml 0.9% Nacl ampoule packed in a unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)

Batch No.	Trial - 001	Trial - 002	Trial - 003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	01-10-2022	01-10-2022	01-10-2022
Date of Initiation	05-10-2022	05-10-2022	05-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Material Loan from Global Pharma **Quantity:** 100 kg **Invoice #** HBGL-2104282045 **Clearance Date:** 21-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.S.7	Please clarify that why primary container (vial) mentioned in the stability data sheet of drug substance, is different than the aluminium container mentioned in **Section 3.2.S.6** as container closure system?	We have used glass vial as primary container for stability study, instead of Aluminium container as specified in section 3.2.S.6 (container Closure System), to verify its long term behaviour in final fill container. Retained samples of each lot kept in aluminium container. Evidence picture attached.
	Please submit quantitative details (volume of the vials & quantity of drug substance per vial) as well as (volume of the aluminium container & quantity of drug substance per vial) used for storage of intermediate (pantroprazole : mannitol 36:64).	30gm sample powder is filled per 10cc glass vial. It fills almost ¾ of glass vial, whereas Aluminum container is of 1 kg fill weight and it also almost ¾ of container capacity.
3.2.P.2.2.1	Please clarify that why completeness and clarity of solution, uniformity of dosage units, absorbance, transmittance, reconstitution time has not been made part of Pharmaceutical equivalence studies while same are the testing parameters of innovator product?	All test has been performed by our laboratory staff however, we have previously included results of only those parameters considered as critical tests to ensure quality of product. Now we have submitted stability sheets with results of all the tests mentioned in the monograph.
3.2.P.2.6	Please submit the stability	Submitted

		details of the powder for solution for injection after reconstitution with documented evidence.		
	3.2.P.5	Please clarify that why completeness and clarity of solution, uniformity of dosage units, absorbance, transmittance, reconstitution time has not been made part of analytical testing parameters while same are the testing parameters of innovator product?	All test has been performed by our laboratory staff however, we have previously included results of only those parameters considered as critical tests to ensure quality of product. Now we have submitted stability sheets with results of all the tests mentioned in the monograph.	
	3.2.P.8	Please clarify that why sample name/ID has been mention "**UNKNOWN**" instead of *(reference standard OR sample's batch #)* in the sample information window?	Since, the HPLC software has been set on default by the engineer of the supplier. Now we have recently make changes in SOPs for control of documentation and accordingly, the name of analyst will appear at the place of name/ID. SOP along with sample chromatogram submitted as Annex-II.	
		Please clarify that why completeness and clarity of solution, uniformity of dosage units, absorbance, transmittance, reconstitution time has not been made part of analytical testing parameters for stability studies while same are the testing parameters of innovator product?	All test has been performed by our laboratory staff however, we have previously included results of only those parameters considered as critical tests to ensure quality of product. Now we have submitted stability sheets with results of all the tests mentioned in the monograph.	

Decision: Approved with Innovator's Specification.

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

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

New License

M/s Trivista Pharmaceuticals (DML # 000952) KPK.

Central Licensing Board in its 285th meeting held on 17th & 18th March 2022 approved the grant of DML # 000952 following Two (02) sections of dosage forms.

Tablet (General) Section.

Capsule (General) Section.

146.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Trivista Pharmaceuticals. (DML # 000952) 8-km, Taxila Khanpur Road, Dist. Haripur KPK.**
	Name, address of Manufacturing site.	M/s Trivista Pharmaceuticals. (DML # 000952) 8-km, Taxila Khanpur Road, Dist. Haripur KPK.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB

	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24299 dated 04-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 27-09-2023 Slip # 409950208155
	The proposed proprietary name / brand name	Dulacta 30 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric coated pellets of Duloxetine HCl 33.7 mg equivalent to Duloxetine..... 30 mg
	Pharmacotherapeutic Group of (API)	Serotonin and nor-epinephrine reuptake inhibitors (SNRIs)
	Pharmaceutical form of applied drug	Oral hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Dulan Capsule 30 mg **Manufacturer:** M/s Hilton
	Name and address of API manufacturer.	**17% Duloxetine HCl EC pellets** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad. **GMP Validity:** Compliant
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (**Drug Substance)**:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months.

		Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (**Drug Product)**:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Dulan 30 mg capsule **Manufactured by:** Hilton Pharma **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**<u>17% Duloxetine HCl EC pellets</u>** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	DXT295		
Description of Pack (Container closure system)	White to off white enteric coated spherical pellets filled in hard gelatin capsule, size '2' with green cap and white body, roperly locked.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	PFT23E04	PFT23E05	PFT23E06
Batch Size	5000 Capsules	5000 Capsules	5000 Capsules
Manufacturing Date	05-2023	05-2023	05-2023
Date of Initiation	23-05-2023	23-05-2023	23-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API procured from local manufacturer approved by DRAP.
4.	Data of stability batches will be supported by attested respective documents like	firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
3.2.P.8	Please submit stability data for the 06th month interval. Please submit anyone chromatogram of your stability data with report format involving tailing factor, theoretical plates & peak resolution parameters of system suitability.	Submitted

Decision: Approved.

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

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

New Licensee: M/s Pharman Pharmaceuticals (Pvt.) Ltd, (DML # 000958), Gujranwala.

Central Licensing Board in its 286th meeting held on 11th May 2022 approved the grant of Drug Manufacturing License *by way of Formulation* w.e.f 10-11-2021 with following three (03) sections of dosage forms.

Tablet (General) Section.
Capsule (General) Section.
Oral Liquid (General) Section.

147.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 23761 dated 27-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-09-2023 Slip # 82199774370
	The proposed proprietary name / brand name	Ibupfen Tablet 200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet: Ibuprofen..... 200 mg
	Pharmacotherapeutic Group of (API)	Analgesic and antipyretic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10s, 14s, 100s, 200s, 500s & 1000s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Neobutinal **Manufacturer:** M/s Schazoo
	Name and address of API manufacturer.	**Name:** M/s Citi Pharma (Pvt) Ltd. **Address:** 3.5-Km Head Balloki Road Phool Nagar Kasur **GMP Validity**: 02-03-2026
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (**Drug Substance)**:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 36 months**. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (**Drug Product)**:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Neo-Butinol **Manufactured by:** Schazoo Pharma **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s Citi Pharma (Pvt) Ltd. **Address:** 3.5-Km Head Balloki Road Phool Nagar Kasur		
API Lot No.	AWS/IBP/22-001/01		
Description of Pack (Container closure system)	White to off white enteric coated spherical pellets filled in hard gelatin capsule, size '2' with green cap and white body, roperly locked.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	BP22-001	BP22-002	BP22-003
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	20-05-2023	20-05-2023	20-05-2023
No. of Batches	03		

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

	Section	Observations	Reply of the firm	
	1.5.6	The Pharmacopeia reference mentioned for drug product is BP while the analytical testing has been done as per USP specification. You are required to submit prescribed fee of PKR 7500/- forchange in specification from BP to USP specification **OR** submit analytical testing results as per BP specifications.	We would like to confirm that our FPP specifications are USP however, it is mistakenly mentioned as BP in Module –I. we have duly submitted the fee for pre-registration variation in the amount of 7500/- with deposit slip # 19250746321 dated 22-11-2023.	
	3.2.P.2.2.1	Please justify that why a local brand Neobutinal tablet by Schazoo has been chosen for Pharmaceutical equivalence studies and comparative dissolution profile of your drug product instead of Innovator brand which is available in the market of Pakistan?	The innovator brand available in Pakistan contains sugar coating; as our product is film coating so that is why we choose the prominent brand available in the market and carried out pharmaceutical equivalence studies.	

Decision: Approved.

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

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

148.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23479 dated 22-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 10-08-2023 Slip # 1666778434
	The proposed proprietary name / brand name	Stomy 40 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient	Each film coated tablet: Famotidine 40mg

	(API) per unit	
	Pharmacotherapeutic Group of (API)	H_2 Receptor Antagonist
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10s, 20s, 30s & 100s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Famot 40 mg Tablet **Manufacturer:** M/s Shaigan Pharmaceuticals
	Name and address of API manufacturer.	**Name:** M/s Vaasavaa Pharmaceuticals (Pvt.) Ltd **Address:** Plot No. C-216 & 217, MIDC ,Chincholi, Solapur-413 255, Maharashtra, INDIA. **GMP Validity**: ***expired on 14-07-2021***
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (**Drug Substance)**:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 48 months**. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (**Drug Product)**:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Ulcenil 40 mg **Manufactured by:** Siza Pharma **Testing Parameters:** USP Specifications

		Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Vaasavaa Pharmaceuticals (Pvt.) Ltd **Address:** Plot No. C-216 & 217, MIDC,Chincholi, Solapur-413 255, Maharashtra, INDIA.		
API Lot No.	***Not provided***		
Description of Pack (Container closure system)	Parrot green, round biconvex tablet embossed with PHARMAN on one side and other side is plane.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	FM22-001	FM22-002	FM22-003
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	12-05-2023	12-05-2023	12-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Evaluator:

Section	Observations
1.6.5	Please submit the GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be in force till date.
3.2.P.1	In Section 1.5.2 of Module I, the label claim describes drug product as **film coated tablet** while in the formulation / pharmaceutical developmentof drug product, ingredients for film coating are not present. You are

		therefore required to submit evidence approval of uncoated tablet of famotidine in reference regulatory authority and also in Pakistan. You are required to submit batch manufacturing record of three stability batches along with Master formula record.	
	3.2.P.8	Please submit DRAP clearance documents for procurement of API.	

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

149.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958)** **Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23480 dated 22-09-2023
	Details of fee submitted	PKR 30,000/-: Dated 10-08-2023 Slip # 21212140134
	The proposed proprietary name / brand name	Cezee Tablets 10 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet: Cetrizine 2HCl 10mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10s, 20s, 30s,100s & 200s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Tablet Baydal **Manufacturer:** M/s Bayer Pakistan
	Name and address of API manufacturer.	**Name:** M/s Sreekara Organics **Address:** 159/A, SVCIE, IDA Bollaram, Jinnaram Mandal,502325, Sanga Reddy, Telangana-India.

		GMP Validity: 24-04-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (**Drug Substance)**:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 60 months**. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH
	Module-III (**Drug Product)**:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Sedil 10 mg **Manufactured by:** Sami Pharmaceuticals **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Sreekara Organics **Address:** 159/A, SVCIE, IDA Bollaram, Jinnaram Mandal,502325, Sanga Reddy, Telangana-India.
API Lot No.	CTZ08721
Description of Pack (Container closure system)	White, oblong shape biconvex film coated tablet with bisect line and printed with P/P on one side and other side is plain.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	CT22-001	CT22-002	CT22-003
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	12-05-2023	12-05-2023	12-05-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Raw Material (130gm) loan from Batala Pharmaceuticals **Quantity:** 29kg **Invoice #** ZHI-C1/6660/1121 **Dated:** 09-11-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit the GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.5	In Section 1.5.6 of Module I, firm submitted reference of **BP specifications** while in the analytical testing parameters of the drug product, **USP Specifications** have been adopted. You are therefore required to submit prescribed fee of PKR 7500/- for change in specification from BP to USP **OR** submit stability data and batch analysis results along with raw data sheets according to BP specifications.	USP Specifications adopted with submission of prescribed fee. *Slip # 0250053700*
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	For the API used in product development and manufacturing of stability batches, please submit COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted

Decision: Approved with USP Specifications.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
150.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958)** **Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24309 dated 04-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 02-10-2023 Slip # 928763867
	The proposed proprietary name / brand name	Omraz Capsule 20 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Enteric coated pellets containing Omeprazole.....20mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	Enteric coated pellets in hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	14s, 28s, 30s,100s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Risek Capsule 20 mg **Manufacturer:** M/s Getz
	Name and address of API manufacturer.	**8.5% Enteric coated pellets of Omeprazole** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad. **GMP Validity:** 13-06-2024
	Module-II (Quality Overall	Firm has submitted QOS as per WHO QOS-PD

	Summary)	template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (**Drug Substance)**:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 36 months**. Temperature: 30°C ± 2°C Humidity: 55% ± 5% RH
	Module-III (**Drug Product)**:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Capsule Risek 20 mg **Manufactured by:** Getz Pharma **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**<u>8.5% Enteric coated pellets of Omeprazole</u>** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
API Lot No.	OMP1227
Description of Pack (Container closure system)	Yellow cap yellow transparent color body hard gelatin capsule.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	OM22-001	OM22-002	OM22-003
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	20-07-2023	20-07-2023	20-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 01 kg Procurement from local manufacturer approved by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit the GMP certificate of API manufacturer issued by regulatory authority of countryof origin and should be in force till date.	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	For the API used in product development and manufacturing of stability batches, please submit COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted
	Please submit calculation of dissolution test as well as assay results as per calculation formula mentioned in USP pharmacopeia.	Submitted
	Please submit chromatograms and calculation sheets for dissolution tests conducted in 0.1N HCl dissolution medium.	Submitted

Decision: Approved.

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

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

151.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958)**

		Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt.) Ltd. (DML # 000958) Khewat # 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24310 dated 04-10-2023
	Details of fee submitted	PKR 30,000/-: Dated 02-10-2023 Slip # 45556711
	The proposed proprietary name / brand name	Omraz Capsule 40 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Enteric coated pellets containing Omeprazole.....40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	Enteric coated pellets in hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	14s, 28s, 30s,100s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Risek Capsule 40 mg **Manufacturer:** M/s Getz
	Name and address of API manufacturer.	**22.5% Enteric coated pellets of Omeprazole** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad. **GMP Validity:** 13-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance and drug product.
	Module-III (**Drug Substance)**:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 36 months**. Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
	Module-III (**Drug Product)**:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Capsule Risek 20 mg **Manufactured by:** Getz Pharma **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**<u>8.5% Enteric coated pellets of Omeprazole</u>** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	OMP1219		
Description of Pack (Container closure system)	Apple green cap transparent color body hard gelatin capsule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	OM22-004	OM22-005	OM22-006
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	21-07-2023	21-07-2023	21-07-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity :** 01 kg Procurement from local manufacturer approved by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit the GMP certificate of API manufacturer issued by regulatory authority of countryof origin and should be in force till date.	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	For the API used in product development and manufacturing of stability batches, please submit COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted
	Please submit calculation of dissolution test as well as assay results as per calculation formula mentioned in USP pharmacopeia.	Submitted
	Please submit chromatograms and calculation sheets for dissolution tests conducted in 0.1N HCl dissolution medium.	Submitted

Decision: Approved

New License:
M/s Fleming Pharmaceutical (DML # 000936), 23-km Lahore – Sheikhupura Road.
Dosage form: Sterile Powder for Injection (Carbapenem).

Central Licensing Board in its 282nd meeting held on 31st September 2021 approved the grant DML # 000944 for following five (05) sections of dosage forms.

Oral Dry Powder for suspension (Penicillin)
Capsule (Penicillin)
Tablet (Penicillin)
Dry Powder Injectable (Penicillin)
Dry Powder Injectable (Carbapenem)

152.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fleming Pharmaceutical (DML # 000936), 23-km Lahore – Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical (DML # 000936) 23-km Lahore – Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer

		Importer Is involved in none of the above (contract giver)
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27156 dated 17-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-09-2023 Slip # 88876131
	The proposed proprietary name / brand name	Flementin Suspension 156.25 mg / 5 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Amoxicillin tri-hydrate equivalent to Amoxicillin .....125 mg Potassium Clavulanate equivalent to Clavulanic Acid..... 31.25 mg
	Pharmacotherapeutic Group of (API)	Combinations of penicillin & beta-lactamase inhibitors
	Pharmaceutical form of applied drug	Oral Powder for reconstitution to form suspension
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's (90ml amber colored glass bottle)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation (PL 04416/0514)
	For generic drugs (me-too status)	**Brand Name:** Augmentin Suspension 156.25mg/5ml **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **GMP Validity:** 17-11-2024 **Potassium Clavulanate: Syloid (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. **GMP Validity:** 05-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin Tri-hydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH **Potassium Clavulanate: Syloid (1:1)** Accelerated stability Data for 6 months. Temperature: 25°C ± 2°C Humidity: 60% ± 5% RH Real time stability data for 36 months. Temperature: 5°C ± 3°C
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Augmentin DS Suspension Manufactured by: GSK Pakistan Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **Potassium Clavulanate: Syloid (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.	
API Lot No.	**Amoxicillin Tri-hydrate**	**Potassium Clavulanate : Syloid (1:1)**
	00130/601/2021	08NB2205007
Description of Pack (Container closure system)	Flementin Suspension is packed in Amber Glass Bottle, further packed in unit carton along with patient leaflet insert.	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 06 months Accelerated: 06 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)	

Batch No.	T-001	T-002	T-003
Batch Size	400 bottles	400 bottles	400 bottles
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	19/11/2022	19/11/2022	19/11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Potassium Clavulanate: Syloid (1:1)** **Dated:** 14-09-2022 **Quantity:** 7 KG Amoxicillin Tri-hydrate has been procured from Pharmagen Limited licensed by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of both API manufacturers issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.2	Please submit results of analytical testing in tabulated form for a comparison of pharmaceutical equivalence between test product and reference product.	Submitted

Decision: Approved.

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

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

153.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fleming Pharmaceutical (DML # 000936), 23-km Lahore – Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical (DML # 000936) 23-km Lahore – Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27157 dated 17-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-09-2023 Slip # 219479025585
	The proposed proprietary name / brand name	Flementin Suspension 312.50 mg / 5 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Amoxicillin tri-hydrate equivalent to Amoxicillin .....250 mg Potassium Clavulanate equivalent to Clavulanic Acid..... 62.5 mg
	Pharmacotherapeutic Group of (API)	Combinations of penicillin & beta-lactamase inhibitors
	Pharmaceutical form of applied drug	Oral Powder for reconstitution to form suspension
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's (90ml amber colored glass bottle)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation (PL 25298/0123)
	For generic drugs (me-too status)	**Brand Name:** Augmentin DS 312.5mg/5ml **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **GMP Validity:** 17-11-2024 **Potassium Clavulanate : Syloid (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. **GMP Validity:** 05-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin Tri-hydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH **Potassium Clavulanate: Syloid (1:1)** Accelerated stability Data for 6 months. Temperature: 25°C ± 2°C Humidity: 60% ± 5% RH Real time stability data for 36 months. Temperature: 5°C ± 3°C
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Augmentin DS Suspension Manufactured by: GSK Pakistan Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **Potassium Clavulanate: Syloid (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	**Amoxicillin Tri-hydrate**	**Potassium Clavulanate : Syloid (1:1)**	
	00130/601/2021	08NB2205007	
Description of Pack (Container closure system)	Flementin Suspension is packed in Amber Glass Bottle, further packed in unit carton along with patient leaflet insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	400 bottles	400 bottles	400 bottles
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	19/11/2022	19/11/2022	19/11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Potassium Clavulanate: Syloid (1:1)** **Dated:** 14-09-2022 **Quantity:** 7 KG Amoxicillin Tri-hydrate has been procured from Pharmagen Limited licensed by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of both API manufacturers issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.2	Please submit results of analytical testing in tabulated form for a comparison of pharmaceutical equivalence between test product and reference product.	Submitted

Decision: Approved.

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

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

154.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fleming Pharmaceutical (DML # 000936), 23-km Lahore – Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical (DML # 000936) 23-km Lahore – Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27158 dated 17-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-09-2023

		Slip # 030363609204
	The proposed proprietary name / brand name	Flementin Suspension 457 mg / 5 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Amoxicillin tri-hydrate equivalent to Amoxicillin .....400 mg Potassium Clavulanate equivalent to Clavulanic Acid..... 57 mg
	Pharmacotherapeutic Group of (API)	Combinations of penicillin & beta-lactamase inhibitors
	Pharmaceutical form of applied drug	Oral Powder for reconstitution to form suspension
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's (70ml amber colored glass bottle)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation (PL 04416/0654)
	For generic drugs (me-too status)	**Brand Name:** Augmentin BD 457mg/5ml **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **GMP Validity:** 17-11-2024 **Potassium Clavulanate: Syloid (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. **GMP Validity:** 05-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin Tri-hydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH

		Potassium Clavulanate: Syloid (1:1) Accelerated stability Data for 6 months. Temperature: 25°C ± 2°C Humidity: 60% ± 5% RH Real time stability data for 36 months. Temperature: 5°C ± 3°C
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Augmentin BD Suspension Manufactured by: GSK Pakistan Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **Potassium Clavulanate: Syloid (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	**Amoxicillin Tri-hydrate**	**Potassium Clavulanate : Syloid (1:1)**	
	00130/601/2021	08NB2205007	
Description of Pack (Container closure system)	Flementin Suspension is packed in Amber Glass Bottle, further packed in unit carton along with patient leaflet insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	368 bottles	368 bottles	368 bottles
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	19/11/2022	19/11/2022	19/11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Potassium Clavulanate: Syloid (1:1)** **Dated:** 14-09-2022 **Quantity:** 7 KG Amoxicillin Tri-hydrate has been procured from Pharmagen Limited licensed by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of both API manufacturers issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.2	Please submit results of analytical testing in tabulated form for a comparison of pharmaceutical equivalence between test product and reference product.	Submitted

Decision: Approved.

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

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

155.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fleming Pharmaceutical (DML # 000936), 23-km Lahore – Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical (DML # 000936) 23-km Lahore – Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27159 dated 17-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-09-2023 Slip # 76587387
	The proposed proprietary name / brand name	Flementin Tablet 375 mg
	Strength / concentration of drug of	Each film coated tablet contains:

	Active Pharmaceutical ingredient (API) per unit	Amoxicillin tri-hydrate equivalent to Amoxicillin .....250 mg Potassium Clavulanate equivalent to Clavulanic Acid..... 125 mg
	Pharmacotherapeutic Group of (API)	Combinations of penicillin & beta-lactamase inhibitors
	Pharmaceutical form of applied drug	Oral Powder for reconstitution to form suspension
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*USFDA approved* Augmentin®
	For generic drugs (me-too status)	**Brand Name:** Augmentin 375 mg tablet **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **GMP Validity:** 17-11-2024 **Potassium Clavulanate: Acicel (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. **GMP Validity:** 05-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin Tri-hydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH **Potassium Clavulanate: Avicel (1:1)** Accelerated stability Data for 6 months. Temperature: 25°C ± 2°C Humidity: 60% ± 5% RH Real time stability data for 36 months.

		Temperature: 5°C ± 3°C
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Augmentin 375mg Tablet Manufactured by: GSK Pakistan Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**<u>Amoxicillin Tri-hydrate</u>** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **<u>Potassium Clavulanate: Avicel (1:1)</u>** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	**Amoxicillin Tri-hydrate**	**Potassium Clavulanate : Syloid (1:1)**	
	00130/601/2021	08NA2203063	
Description of Pack (Container closure system)	Flementin tablets are in ALU-ALU packing, further packed in unit carton along with patient leaflet insert..		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	28/11/2022	28/11/2022	28/11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Potassium Clavulanate: Avicel (1:1)** **Dated:** 14-09-2022 **Quantity:** 7 KG Amoxicillin Tri-hydrate has been procured from Pharmagen Limited licensed by DRAP.
4.	Data of stability batches will be supported by attested respective documents like	firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of both API manufacturers issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.2	Please submit results of analytical testing in tabulated form for a comparison of pharmaceutical equivalence between test product and reference product.	Submitted

Decision: Approved.

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

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

156.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fleming Pharmaceutical (DML # 000936), 23-km Lahore – Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical (DML # 000936) 23-km Lahore – Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27159 dated 17-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-09-2023 Slip # 027494154307
	The proposed proprietary name / brand name	Flementin Tablet 625 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amoxicillin tri-hydrate equivalent to Amoxicillin .....500 mg Potassium Clavulanate equivalent to Clavulanic Acid..... 125 mg
	Pharmacotherapeutic Group of (API)	Combinations of penicillin & beta-lactamase inhibitors
	Pharmaceutical form of applied drug	Oral Powder for reconstitution to form suspension

	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*USFDA approved* Augmentin®
	For generic drugs (me-too status)	**Brand Name:** Augmentin 625 mg tablet **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **GMP Validity:** 17-11-2024 **Potassium Clavulanate: Acicel (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. **GMP Validity:** 05-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin Tri-hydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH **Potassium Clavulanate: Avicel (1:1)** Accelerated stability Data for 6 months. Temperature: 25°C ± 2°C Humidity: 60% ± 5% RH Real time stability data for 36 months. Temperature: 5°C ± 3°C
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Augmentin 625mg Tablet Manufactured by: GSK Pakistan Testing Parameters: BP Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**<u>Amoxicillin Tri-hydrate</u>** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **<u>Potassium Clavulanate: Avicel (1:1)</u>** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	**Amoxicillin Tri-hydrate**	**Potassium Clavulanate : Syloid (1:1)**	
	00130/601/2021	08NA2203063	
Description of Pack (Container closure system)	Flementin tablets are in ALU-ALU packing, further packed in unit carton along with patient leaflet insert..		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	28/11/2022	28/11/2022	28/11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Potassium Clavulanate: Avicel (1:1)** **Dated:** 14-09-2022 **Quantity:** 7 KG Amoxicillin Tri-hydrate has been procured from Pharmagen Limited licensed by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity

		monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of both API manufacturers issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.2	Please submit results of analytical testing in tabulated form for a comparison of pharmaceutical equivalence between test product and reference product.	Submitted

Decision: Approved.

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

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

157.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fleming Pharmaceutical (DML # 000936), 23-km Lahore – Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical (DML # 000936) 23-km Lahore – Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27161 dated 17-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 25-09-2023 Slip # 979117280
	The proposed proprietary name / brand name	Flementin Tablet 1000 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amoxicillin tri-hydrate equivalent to Amoxicillin .....875 mg Potassium Clavulanate equivalent to Clavulanic Acid..... 125 mg
	Pharmacotherapeutic Group of (API)	Combinations of penicillin & beta-lactamase inhibitors
	Pharmaceutical form of applied drug	Oral Powder for reconstitution to form suspension
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	6's
	Proposed unit price	As per SRO
	The status in reference regulatory	*USFDA approved* Augmentin®

	authorities	
	For generic drugs (me-too status)	**Brand Name:** Augmentin 1000 mg tablet **Manufacturer:** M/s GSK
	Name and address of API manufacturer.	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **GMP Validity:** 17-11-2024 **Potassium Clavulanate: Acicel (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. **GMP Validity:** 05-06-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Amoxicillin Tri-hydrate** Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 48 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH **Potassium Clavulanate: Avicel (1:1)** Accelerated stability Data for 6 months. Temperature: 25°C ± 2°C Humidity: 60% ± 5% RH Real time stability data for 36 months. Temperature: 5°C ± 3°C
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Augmentin 1000 mg Tablet Manufactured by: GSK Pakistan Testing Parameters: BP Specifications

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

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Tri-hydrate** **Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **Potassium Clavulanate: Avicel (1:1)** **Name:** M/s Sino Pharm Weiqida Pharmaceutical **Address:** Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	**Amoxicillin Tri-hydrate**	**Potassium Clavulanate : Syloid (1:1)**	
	00130/601/2021	08NA2203063	
Description of Pack (Container closure system)	Flementin tablets are in ALU-ALU packing, further packed in unit carton along with patient leaflet insert..		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2750 tablets	2750 tablets	2750 tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	28/11/2022	28/11/2022	28/11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Potassium Clavulanate: Avicel (1:1)** **Dated:** 14-09-2022 **Quantity:** 7 KG Amoxicillin Tri-hydrate has been procured from Pharmagen Limited licensed by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of both API manufacturers issuedby regulatory authority of country of origin and should be in force till date.	Submitted

	3.2.P.2	Please submit results of analytical testing in tabulated form for a comparison of pharmaceutical equivalence between test product and reference product.	Submitted	

Decision: Approved.

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

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

New License: M/s Oncogen Pharma (Private) Limited (DML # 000960), Karachi.
Dosage form: Tablet (Oncology) Section.

Under Drugs (Licensing, Registering & Advertising) Rules 1976, Central Licensing Board of DRAP, in its 287th meeting held on 24th June,2022 approved the grant of Drug Manufacturing License (DML) # 000960 for following two (02) sections of dosage forms.

Tablet (Oncology)
Capsule (Oncology)

158.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27741 dated 28-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 11-10-2023 Slip # 54443245761
	The proposed proprietary name / brand name	Tablet Mynolic 180 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Mycophenolic acid (as mycophenolate Sodium) ……..…… 180 mg
	Pharmacotherapeutic Group of (API)	Immunosuppressive agent Inhibitor of guanosine nucleotide synthesis
	Pharmaceutical form of applied drug	Enteric coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	6 x 10s (6 blisters containing 10 tablets) 12 x 10s (12 blister containing 10 tablets)

	Proposed unit price	6 x 10s (6 blisters containing 10 tablets) PKR 16,000/- 12 x 10s (12 blister containing 10 tablets) PKR 8000/-
	The status in reference regulatory authorities	USFDA approved Myfortic®
	For generic drugs (me-too status)	Myfortic tablet 180 mg by Novartis
	Name and address of API manufacturer.	**Mycophenolate Sodium** Name: M/s Concord Biotech Ltd. Address: Plot # 1482 – 1486, TRASAD Road, Dholka, District Ahmedabad, India. GMP Validity: 14-07-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Myfortic 180 mg Tablets **Manufactured by: Novartis, Germany** **LOT #** LX6013 **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Mycophenolate Sodium** Name: M/s Concord Biotech Ltd. Address: Plot # 1482 – 1486, TRASAD Road, Dholka, District Ahmedabad, India.		
API Lot No.	0305A622291, 0305A622268		
Description of Pack (Container closure system)	ALU-ALU Blister pack of 60 tablets in unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	004NS03-180	004NS04-180	004NS05-180
Batch Size	4200 tablets	4200 tablets	4200 tablets
Manufacturing Date	04-2023	05-2023	05-2023
Date of Initiation	22/05/2023	22/05/2023	22/05/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Form 6 issuance date:** 30-07-2022 **Quantity:** 13.4kg **Invoice #** VXL/EXP/011 **Dated:** 18-11-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

The API in the drug product belongs to immunosuppressant class of drugs which is allowed to be manufactured in General facility with precautionary measures while the manufacturing facility of drug product manufacturer is for dosage forms of oncology (Tablet & capsules).

Registration Board was apprised that drugs products falling in WHO ATC code L04 were being allowed to be manufactured in general section with precautionary measures, and accordingly, the firm has already installed additional precautionary measures including installation of isolators, personal protective equipment (PPE) and proper cleaning validation processes etc.

Decision: Registration Board after thorough deliberation, while considering the fact that the firm has already installed additional precautionary measures including installation of isolators, personal protective equipment (PPE) and proper cleaning validation processes etc, decided to approve the product.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
159.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Oncogen Pharma (Private) Limited (DML # 000960)** **Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27742 dated 28-11-2023
	Details of fee submitted	PKR 30,000/-: Dated 11-10-2023 Slip # 0101985625
	The proposed proprietary name / brand name	Tablet Mynolic 360 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Mycophenolic acid (as mycophenolate Sodium) ……..…… 360 mg
	Pharmacotherapeutic Group of (API)	Immunosuppresive agent Inhibitor of guanosine nucleotide synthesis
	Pharmaceutical form of applied drug	Enteric coated Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	6 x 10s (6 blisters containing 10 tablets) 12 x 10s (12 blister containing 10 tablets)
	Proposed unit price	6 x 10s (6 blisters containing 10 tablets) PKR 14,000/- 12 x 10s (12 blister containing 10 tablets) PKR 28000/-
	The status in reference regulatory authorities	USFDA approved Myfortic®
	For generic drugs (me-too status)	Myfortic tablet 360 mg by Novartis
	Name and address of API manufacturer.	**<u>Mycophenolate Sodium</u>** Name: M/s Concord Biotech Ltd.

		Address: Plot # 1482 – 1486, TRASAD Road, Dholka, District Ahmedabad, India. GMP Validity: 14-07-2024
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Myfortic 360 mg Tablets **Manufactured by: Novartis, Germany** **LOT #** LX617 **Testing Parameters:** USP Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**<u>Mycophenolate Sodium</u>** Name: M/s Concord Biotech Ltd. Address: Plot # 1482 – 1486, TRASAD Road, Dholka, District Ahmedabad, India.
API Lot No.	0305A622291, 0305A622268
Description of Pack (Container closure system)	ALU-ALU Blister pack of 60 tablets in unit carton along with leaflet.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	004NS03-360	004NS04-360	004NS05-360
Batch Size	3570 tablets	3570 tablets	4200 tablets
Manufacturing Date	04-2023	05-2023	05-2023
Date of Initiation	22/05/2023	22/05/2023	22/05/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Form 6 issuance date:** 30-07-2022 **Quantity:** 13.4kg **Invoice #** VXL/EXP/011 **Dated:** 18-11-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

The API in the drug product belongs to immunosuppressant class of drugs which is allowed to be manufactured in General facility with precautionary measures while the manufacturing facility of drug product manufacturer is for dosage forms of oncology (Tablet & capsules).

Registration Board was apprised that drugs products falling in WHO ATC code L04 were being allowed to be manufactured in general section with precautionary measures, and accordingly, the firm has already installed additional precautionary measures including installation of isolators, personal protective equipment (PPE) and proper cleaning validation processes etc.

Decision: Registration Board after thorough deliberation, while considering the fact that the firm has already installed additional precautionary measures including installation of isolators, personal protective equipment (PPE) and proper cleaning validation processes etc, decided to approve the product.

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

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

160.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Oncogen Pharma (Private) Limited (DML # 000960)** **Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.**

	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	BSU-S77-86X1 dated 05-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 24-10-2023 Slip # 496440729
	The proposed proprietary name / brand name	Ibralib Tablet 125mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Palbociclib 125mg
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors ATC code: LO1EFO1
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	**Proposed Pack Size:** 21's 3 x 7's (3 blister containing 7 Tablets) M.R.P: 324,800/= **Proposed Pack Size:** 7's 1 x 7's (1 blister containing 7 Tablets) M.R.P: 108,2671
	Proposed unit price	**Proposed Pack Size:** 21's 3 x 7's (3 blister containing 7 Tablets) M.R.P: 324,800/= **Proposed Pack Size:** 7's 1 x 7's (1 blister containing 7 Tablets) M.R.P: 108,2671
	The status in reference regulatory authorities	USFDA approved Ibrance®
	For generic drugs (me-too status)	**Brand name:** Ibrance Tablet 125mg **Manufacturer:** Pfizer (Pakistan) Limited Reg. No. 114207
	Name and address of API manufacturer.	**Name:** M/s. Cdymax (India) Pharma Private Limited, **Address:**116/117, KIADB Industrial Area, Jigani, 2nd Phase, Bangalore5601 05, Karnataka, India. **GMP validity:** 01-07-2022

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Palbace Tablet 125 mg **Manufactured by:** Pfizer, Germany. **LOT #** 6M4682 **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s. Cdymax (India) Pharma Private Limited, **Address:**116/117, KIADB Industrial Area, Jigani, 2nd Phase, Bangalore5601 05, Karnataka, India.
API Lot No.	PBCD22002
Description of Pack (Container closure system)	Alu-Alu foil blister Pack of 2l Tablets in unit carton along with leaflet
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	005NS03-125	005NS04-125	005NS05-125
Batch Size	2100 tablets	2100 tablets	2100 tablets
Manufacturing Date	May-2023	May-2023	May-2023
Date of Initiation	13-Jun-2023	13-Jun-2023	13-Jun-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Form 6 issuance date:** 01-09-2022 **Quantity:** 1.4kg **Invoice #** EX0106/2022-2023 **Dated:** 07-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit within use-by date / valid GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.P.8	Please submit the stability data along with required documents/information for the interval of 06th month of stability for both accelerated and long term storage conditions.	Submitted

Decision: Approved with Innovator Specifications.

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

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

161.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License

	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	8PJ-XJH-RGG1 dated 05-12-2023
	Details of fee submitted	PKR 30,000/-: Dated 24-10-2023 Slip # 5791063219
	The proposed proprietary name / brand name	Ibralib Tablet 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Palbociclib 100mg
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors ATC code: LO1EFO1
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	**Proposed Pack Size:** 3 x 7's (3 blister containing 7 Tablets) M.R.P: 321,600/= **Proposed Pack Size:** 1 x 7's (1 blister containing 7 Tablets) M.R.P: 107,200/
	Proposed unit price	**Proposed Pack Size:** 3 x 7's (3 blister containing 7 Tablets) M.R.P: 321,600/= **Proposed Pack Size:** 1 x 7's (1 blister containing 7 Tablets) M.R.P: 107,200/
	The status in reference regulatory authorities	USFDA approved Ibrance®
	For generic drugs (me-too status)	**Brand name:** Ibrance Tablet 100mg **Manufacturer:** Pfizer (Pakistan) Limited Reg. No. 114206
	Name and address of API manufacturer.	**Name:** M/s. Cdymax (India) Pharma Private Limited, **Address:**116/117, KIADB Industrial Area, Jigani, 2nd Phase, Bangalore5601 05, Karnataka, India. **GMP validity:** 01-07-2022
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description

		of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Palbace Tablet 100 mg **Manufactured by:** Pfizer, Germany. **LOT #** GY6742 **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s. Cdymax (India) Pharma Private Limited, **Address:**116/117, KIADB Industrial Area, Jigani, 2nd Phase, Bangalore5601 05, Karnataka, India.		
API Lot No.	PBCD22003		
Description of Pack (Container closure system)	Alu-Alu foil blister Pack of 2l Tablets in unit carton along with leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	005NS03-100	005NS04-100	005NS05-100
Batch Size	2200 tablets	2200 tablets	2200 tablets
Manufacturing Date	May-2023	May-2023	May-2023
Date of Initiation	13-Jun-2023	13-Jun-2023	13-Jun-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Form 6 issuance date:** 01-09-2022 **Quantity:** 1.4kg **Invoice #** EX0106/2022-2023 **Dated:** 07-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit within use-by date / valid GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.P.8	Please submit the stability data along with required documents/information for the interval of 06th month of stability for both accelerated and long term storage conditions.	Submitted

Decision: Approved with Innovator Specifications.

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

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

162.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma (Private) Limited (DML # 000960) Plot # WH-26 &27-A3, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer Importer Is involved in none of the above (contract giver)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	New Section granted by CLB
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	7JJ-4V8-VXE6 dated 05-12-2023

	Details of fee submitted	PKR 30,000/-: Dated 24-10-2023 Slip # 5791063219
	The proposed proprietary name / brand name	Ibralib Tablet 75 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Palbociclib .....75 mg
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors ATC code: LO1EFO1
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	**Proposed Pack Size:** 3 x 7's (3 blister containing 7 Tablets) M.R.P: 321,600/= **Proposed Pack Size:** 1 x 7's (1 blister containing 7 Tablets) M.R.P: 107,200/
	Proposed unit price	**Proposed Pack Size:** 3 x 7's (3 blister containing 7 Tablets) M.R.P: 321,600/= **Proposed Pack Size:** 1 x 7's (1 blister containing 7 Tablets) M.R.P: 107,200/
	The status in reference regulatory authorities	USFDA approved Ibrance®
	For generic drugs (me-too status)	**Brand name:** Ibrance Tablet 75mg **Manufacturer:** Pfizer (Pakistan) Limited Reg. No. 114205
	Name and address of API manufacturer.	**Name:** M/s. Cdymax (India) Pharma Private Limited, **Address:**116/117, KIADB Industrial Area, Jigani, 2nd Phase, Bangalore5601 05, Karnataka, India. **GMP validity:** 01-07-2022
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability Data for 6 months. Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH Real time stability data for 36 months. Temperature: 30°C ± 2°C

		Humidity: 75% ± 5% RH
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Palbace Tablet 75 mg **Manufactured by:** Pfizer, Germany. **LOT #** FX4531 **Testing Parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s. Cdymax (India) Pharma Private Limited, **Address:**116/117, KIADB Industrial Area, Jigani, 2nd Phase, Bangalore5601 05, Karnataka, India.		
API Lot No.	PBCD22003		
Description of Pack (Container closure system)	Alu-Alu foil blister Pack of 2l Tablets in unit carton along with leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	005NS03-75	005NS04-75	005NS05-75
Batch Size	2450 tablets	2450 tablets	2450 tablets
Manufacturing Date	May-2023	May-2023	May-2023
Date of Initiation	13-Jun-2023	13-Jun-2023	13-Jun-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Form 6 issuance date:** 01-09-2022 **Quantity:** 1.4kg **Invoice #** EX0106/2022-2023 **Dated:** 07-10-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	firm has submitted analytical record for product testing.

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

Remarks of Evaluator:

Section	Observations	Status
1.6.5	Please submit within use-by date / valid GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Submitted
3.2.P.8	Please submit the stability data along with required documents/information for the interval of 06th month of stability for both accelerated and long term storage conditions.	Submitted

Decision: Approved with Innovator Specifications.

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

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

Item No. 02: Cases of Form 5 / Form 5-D with stability studies.

163.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt) Ltd.** **(DML # 000789)** **Plot No. 129 Sundar Industrial Estate Lahore**
	Diary No. Date of R& I & fee	Dy. No:52; Rs. 20,000/- Dated: 21-03-2014
	Brand Name +Dosage Form + Strength	Brilliant 90mg Tablet
	Composition	Each film coated tablet contains: Ticagrelor.....90mg
	Pharmacological Group	Thromobolytics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	10"s, As per SRO
	Approval status of product in Reference Regulator Authorities	**BRILINTA ® 90 mg Tablets** by AstraZeneca (USFDA Approved)
	Me-too status	Virata by CCL
	GMP status	Last Inspection report 03-04-2023, firm had maintained conformance to GMP compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator	Fee challan photocopy is attached Me-too status cannot be confirmed Firm has claimed in house specs but not providedthe following documents in the light of decision of 267th RB meeting
STABILITY STUDY DATA		
Manufacturer of API	**Name:** Nantong Chanyoo Pharmatech Co. Ltd. **Address:** No. 02, Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China. **GMP validity:** 21-02-2026	

API Lot No.	RD-TG-201808021		
Description of Pack (Container closure system)	Tablets are packed in Alu-Alu blister & introduced in a card board box.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	**TT1001**	**TT1002**	**TT1003**
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	08-08-2020	08-08-2020	08-08-2020
No. of Batches	03		
Date of Submission	18-03-2021 (8855)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents to Be Provided	Status
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	Real time conditions on Zone IV-A,12 months Accelerated conditions -→ 06 months
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
vi.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** CY118242 **Dated:** 08-01-2019 **Quantity:** 1.0 kg
vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Not required
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Submitted
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA,	Submitted

	summary data sheets etc.	
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision in 271st meeting of DRB:
Deferred for the following:
Evidence of me-too status.
Verification of fee challan of Rs.20,000/- from B&A, Division.

REMARKS OF EVALUATOR:

S #	Observations	Reply of the firm
i.	For confirmation of GMP status of oral dosage form manufacturing facility - Tablet (General) Section, please submit latest inspection report of your firm conducted within last 03 years **OR** GMP certificate issued by DRAP.	Submitted
ii.	GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be in force till date.	Submitted
iii.	COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted
iv.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Submitted
v.	Stability study data of API from API manufacturer.	Submitted
vi.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
vii.	Protocols followed for conduction of stability study.	Submitted
viii.	Details of procedures for analytical method used for analysis of FPP.	Submitted
ix.	Complete batch manufacturing record of three stability batches.	Submitted
x.	Record of comparative dissolution data.	Submitted

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

164.	**Name and address of manufacturer / Applicant**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd.** **(DML # 000707)** **Plot No. 209 Sector 23 Korangi Industrial Area Karachi.**
	Diary No. Date of R& I & fee	Dy.No. 33691, Dated:10-10-2018, Rs.20,000/-
	Brand Name +Dosage Form + Strength	Boschofen 400mg/4ml Injection
	Composition	Each 4ml Ampoule Contains: Ibuprofen B.P…….400mg
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	1's & 5's : As per SRO

	Approval status of product in Reference Regulator Authorities	CALDOLOR 400mg/4ml TGA Australia approved
	Me-too status	Xaleve 400mg/4ml of M/s Hudson Pharma (Reg # 093088)
	GMP status	Last GMP inspection conducted on 13-04-2021 and report concludes firm was considered to be operating at an acceptable of compliance with GMP."
	Remarks of the Evaluator	Stability molecule

Decision in 293rd meeting of DRB:
Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	Hubei Granules Bio Cause Pharma - China
API Lot No.	C100-1904272M
Description of Pack (Container closure system)	Clear Glass Ampoule
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)

Batch No.	**TR-BFINJ-02**	**TR-BFINJ-03**	**TR-BFINJ-04**
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	03-2020	03-2020	03-2020
No. of Batches	03		
Date of Submission	16-11-2021 (Dy. # 31560)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents to Be Provided	Status
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	Submitted
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
vi.	Documents for the procurement of API with approval from DRAP (in case of	Submitted

	import).	
vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Not required
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Submitted
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR:

S#	Observations	Reply of the firm
i.	GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be in force till date	Submitted
ii.	COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted
iii.	Stability study data of API from API manufacturer.	Submitted
iv.	Documents for the procurement of API with approval from DRAP (in case of import)	Submitted
v.	Complete batch manufacturing record of three stability batches.	Submitted

Decision: Approved.

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

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

165.	**Name and address of manufacturer / Applicant**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd.** **(DML # 000707)** **Plot No. 209 Sector 23 Korangi Industrial Area Karachi.**
	Diary No. Date of R& I & fee	Dy.No. 12248, Dated:03-04-2018, Rs.50,000/- Dated :28-03-2018.
	Brand Name +Dosage Form + Strength	Boschofen 600mg/100ml Injection
	Composition	Each 100ml vial contains: Ibuprofen B.P…….600mg
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specification

	Pack size & Demanded Price	1's & 5's : As per SRO
	Approval status of product in Reference Regulator Authorities	Ibuprofen B. Braun 600mg/100ml Solution for infusion HPRA Ireland approved
	Me-too status	Ubrof Infusion (Reg # 105263) by Sami Pharma
	GMP status	Last GMP inspection conducted on 13-04-2021 and report concludes firm was considered to be operating at an acceptable of compliance with GMP."
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	Bio Cause Pharmaceuticals (Pvt.) Ltd - China
API Lot No.	C100-1904272M
Description of Pack (Container closure system)	Clear Glass vial 100 ml infusion
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)

Batch No.	**TR-P2-06**	**TR-P2-05**	**TR-P2-04**
Batch Size	200 vials	200 vials	200 vials
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	11-2019	11-2019	11-2019
No. of Batches	03		
Date of Submission	26-11-2021 (Dy. # 32354)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	**Documents to Be Provided**	**Status**
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	Submitted
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
vi.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Submitted
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Submitted
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR:

Please submit following shortcomings for further evaluation of your application.

Observations	Status
GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be in force till date.	Submitted
COA of API issued by drug substance manufacturer as well as drug product manufacturer.	Submitted
Stability study data of API from API manufacturer.	Submitted
Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
Complete batch manufacturing record of three stability batches.	Submitted

Decision: Approved.

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

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

166.	**Name and address of manufacturer / Applicant**	**M/s S.J & G. Fazul Ellahie (Pvt) Ltd. E/46 S.I.T.E Karachi (DML # 000083)**
	Diary No. Date of R& I & fee	Dy.No. 19297, Dated:27-10-2017, Rs.50,000/- Dated :28-10-2017.
	Brand Name +Dosage Form + Strength	Ates Injection 800mg/8ml
	Composition	Each ml vial contains: Ibuprofen..... 100mg
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	1's & 5's : As per SRO
	Approval status of product in Reference Regulator Authorities	TGA Australia approved

	Me-too status	Ubrof 800mg/8ml (Reg # 105262) by Sami Pharma
	GMP status	Last GMP inspection conducted on 25-08-2023 and report concludes firm was considered to be operating at an acceptable of compliance with GMP."
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	Bio Cause Pharmaceuticals (Pvt.) Ltd - China
API Lot No.	C100-2003026M
Description of Pack (Container closure system)	Clear Glass vial 100 ml infusion
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)

Batch No.	**TR-054-21**	**TR-055-21**	**TR-056-21**
Batch Size	100 vials	100 vials	100 vials
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	12-05-2021	12-05-2021	12-05-2021
No. of Batches	03		
Date of Submission	08-11-2021 (Dy. # 30566)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents to Be Provided	Status
i.	Reference of previous approval of applications with stability study data of the firm	Not required
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 72 months**. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Name:** Hubei Granules Bio-cause Phrmaceutical company **Address:** 122 Yamgwan Road, Jingmen Hubei China. **GMP Validity:** 28-08-2022
vi.	Documents for the procurement of API with approval from DRAP (in case of	**Quantity:** 420 gm **Form 6 issuance date:** 20-11-2020

	import).	
vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Not required
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Not required
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR:

S #	Observations	Reply of the firm
i.	GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be in force till date.	Submitted
ii.	Stability data of three batches along with chromatograms and raw data for the 06th month interval.	Submitted

Decision: Approved.

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

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

167.	**Name and address of manufacturer / Applicant**	**M/s S.J & G. Fazul Ellahie (Pvt) Ltd. E/46 S.I.T.E Karachi (DML # 000083)**
	Diary No. Date of R& I & fee	Dy.No. 19298, Dated:27-10-2017, Rs.50,000/- Dated :28-10-2017.
	Brand Name +Dosage Form + Strength	Ates Injection 400mg/4ml
	Composition	Each ml vial contains: Ibuprofen..... 100mg
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	1's & 5's : As per SRO
	Approval status of product in Reference Regulator Authorities	TGA Australia approved
	Me-too status	Xaleve 400mg/4ml of M/s Hudson Pharma (Reg # 093088)
	GMP status	Last GMP inspection conducted on 25-08-2023 and

		report concludes firm was considered to be operating at an acceptable of compliance with GMP."
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	Bio Cause Pharmaceuticals (Pvt.) Ltd - China		
API Lot No.	C100-2003026M		
Description of Pack (Container closure system)	Clear Glass vial 100 ml infusion		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)		
Batch No.	**TR-054-21**	**TR-055-21**	**TR-056-21**
Batch Size	100 vials	100 vials	100 vials
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	12-05-2021	12-05-2021	12-05-2021
No. of Batches	03		
Date of Submission	19-11-2021 (Dy. # 30565)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. #	**Documents to Be Provided**	**Status**
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 72 months**. Temperature: 30°C ± 2°C Humidity: 75% ± 5% RH
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Name:** Hubei Granules Bio-cause Phrmaceutical company **Address:** 122 Yamgwan Road, Jingmen Hubei China. **GMP Validity:** 28-08-2022
vi.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 420 gm **Form 6 issuance date:** 20-11-2020
vii.	Protocols followed for conduction of	Submitted

	stability study	
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Not required
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Not required
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR:

Please submit following shortcomings for further evaluation of your application.

S #	Observations	Reply of the firm
i.	GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be in force till date.	Submitted
ii.	Stability data of three batches along with chromatograms and raw data for the 06th month interval.	Submitted

Decision: Approved.

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

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

168.	**Name and address of manufacturer / Applicant**	**M/s Horizon Healthcare (Pvt) Ltd.** **(DML # 000782)** **Plot No.33, Sundar Industrial Estate, Lahore.**
	Diary No. Date of R& I & fee	Dy.No. 39958, Dated:04-12-2018, Rs.20,000/- Dated :14-12-2018.
	Brand Name +Dosage Form + Strength	Trika 90mg Tablet
	Composition	Each film coated tablet contains: Ticagrelor.....90mg
	Pharmacological Group	Thromobolytics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	10"s, As per SRO
	Approval status of product in Reference Regulator Authorities	**BRILINTA ® 90 mg Tablets** by AstraZeneca (USFDA Approved)
	Me-too status	Virata by CCL
	GMP status	Not submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	**Name:** JIANGXI SYNERGY PHARMACEUTICAL CO. LTD. **Address:** Jiangxi Fengxin Industrial Park, Fengxin 330700, Jiangxi Province, China.		
API Lot No.	*Not provided*		
Description of Pack (Container closure system)	*Not provided*		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)		
Batch No.	TGH-001	TGH-002	TGH-003
Batch Size	*Not provided*	*Not provided*	*Not provided*
Manufacturing Date	*Not provided*	*Not provided*	*Not provided*
Date of Initiation	*Not provided*	*Not provided*	*Not provided*
No. of Batches	03		
Date of Submission	30-06-2021 (Dy. # 18378)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. #	**Documents to Be Provided**	**Status**
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Not submitted
iv.	Stability study data of API from API manufacturer	Not submitted
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
vi.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** JXSG181028 **Dated:** 22-03-2019 **Quantity:** 40kg
vii.	Protocols followed for conduction of stability study	Not submitted
viii.	Method used for analysis of FPP	Not submitted
ix.	Drug-excipients compatibility studies (where applicable)	Not submitted
x.	Complete batch manufacturing record of three stability batches.	Not submitted

xi.	Record of comparative dissolution data (where applicable)	Not submitted
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Partially submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

REMARKS OF EVALUATOR:

Please submit following shortcomings for further evaluation of your application.

Inspection report of drug product manufacturing facility conducted by DRAP within last three (03) years **OR** GMP certificate issued by DRAP which should be valid till date.

GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be in force till date.

Please submit stability data sheet containing information about three stability batches regarding Batch #, Batch size, details of primary container of the drug product, stability storage conditions of drug product, manufacturing date, expiry date, API Lot # used in manufacturing of drug product, date of initiating testing, comparison of results of testing along with limits in tabulated form for 0,3,6-month interval.

Calculation sheets for assay and dissolution tests of drug products.

Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.

Stability study data of API from API manufacturer.

Protocols followed for conduction of stability study.

Method used for analysis of FPP.

Drug-excipients compatibility studies (where applicable)

Complete batch manufacturing record of three stability batches.

Record sheets of comparative dissolution data along with information regarding batch #, manufacturing date, expiry date of innovator /reference product used for comparison of dissolution profile in three mediums.

Decision:

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

169.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. (DML # 000590)** **28-km,Ferozepur Road, Lahore**
	Diary No. Date of R& I & fee	Dy.No. 24659, Dated:15-12-2017, Rs.50,000/- Dated :15-12-2017.
	Brand Name +Dosage Form + Strength	Angiocare 90mg Tablet
	Composition	Each film coated tablet contains: Ticagrelor.....90mg
	Pharmacological Group	Thromobolytics
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	10"s, As per SRO
	Approval status of product in Reference Regulator Authorities	**BRILINTA ® 90 mg Tablets** by AstraZeneca (USFDA Approved)

	Me-too status	Virata by CCL
	GMP status	Inspection report dated 06-08-2021 submitted. cGMP Status - Good
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	**Name:** Nantong Chanyoo Pharmatech Co. Ltd. **Address:** No. 02, Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China. **GMP validity:** 21-02-2026
API Lot No.	RD-TG-202005061
Description of Pack (Container closure system)	ALU-ALU blister
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)

Batch No.	RD/PR20-034/T2/S1	RD/PR20-034/T2/S2	RD/PR20-034/T2/S3
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	18-01-2021	18-01-2021	18-01-2021
No. of Batches	03		
Date of Submission	20-09-2021 (Dy. # 26032)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents to Be Provided	Status
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 24 months.** Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
vi.	Documents for the procurement of API with approval from DRAP (in case of	**Invoice#** CYI20225 **Clearance Date:** 16-07-2020

	import).	**Quantity:** 1.5kg
vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Submitted
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Submitted
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR:

S #	Observations	Reply of the firm
1.	Inspection report of drug product manufacturing facility conducted by DRAP within last three (03) years **OR** GMP certificate issued by DRAP which should be valid till date.	Submitted
2.	GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be in force till date.	Submitted

Decision: Approved.

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

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

170.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. (DML # 000590)** **28-km,Ferozepur Road, Lahore**
	Diary No. Date of R& I & fee	Dy.No. 24660, Dated:15-12-2017, Rs.50,000/- Dated :15-12-2017.
	Brand Name +Dosage Form + Strength	Angiocare 60mg Tablet
	Composition	Each film coated tablet contains: Ticagrelor.....60mg
	Pharmacological Group	Thromobolytics
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	10"s, As per SRO
	Approval status of product in Reference Regulator Authorities	**BRILINTA ® 60 mg Tablets** by AstraZeneca (USFDA Approved)

	Me-too status	Virata by CCL
	GMP status	Inspection report dated 06-08-2021 submitted. cGMP Status - Good
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	**Name:** Nantong Chanyoo Pharmatech Co. Ltd. **Address:** No. 02, Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China. **GMP validity:** 17-08-2024
API Lot No.	RD-TG-202005061
Description of Pack (Container closure system)	ALU-ALU blister
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (months)

Batch No.	RD/PR20-033/T2/S1	RD/PR20-033/T2/S2	RD/PR20-033/T2/S3
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	11-2020	11-2020	01-2021
Date of Initiation	05-11-2020	05-11-2021	18-01-2021
No. of Batches	03		
Date of Submission	20-09-2021 (Dy. # 26032)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents to Be Provided	Status
i.	Reference of previous approval of applications with stability study data of the firm	Submitted
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
iii.	Method used for analysis of API fromboth API Manufacturer and Finished Product Manufacturer	Submitted
iv.	Stability study data of API from API manufacturer	**Accelerated stability Data for 6 months.** Temperature: 40°C ± 2°C Humidity: 75% ± 5% RH **Real time stability data for 24 months.** Temperature: 30°C ± 2°C Humidity: 65% ± 5% RH
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
vi.	Documents for the procurement of API with approval from DRAP (in case of	**Invoice#** CYI20225 **Clearance Date:** 16-07-2020

	import).	**Quantity:** 1.5kg
vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted
ix.	Drug-excipients compatibility studies (where applicable)	Submitted
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Submitted
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
REMARKS OF EVALUATOR:		
Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Item No. 03: Import Cases

171.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0065-016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan. Address of Godown: NA Validity: 06.02.2024 Status: VALID
	Name and address of marketing authorization holder (abroad)	**EVER VALINJECT GmbH** Oberburgau 3 4866 Unterach am Attersee **Austria.**
	Name, address of manufacturer(s)	**Bulk Manufacturer, primary packaging & Product release.** EVER PHARMA Jena GmbH, Otto-Schott-StraBe 15, 07745 Jena, **Germany**. **Secondary Packaging and Labelling:**

		Ever Pharma Jena GmbH, Brusseler StraBe 18, 07747 Jena, **Germany.**
	Name of exporting country	**Austria**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 19th May 2023 **CoPP:** Firm has submitted original, legalized CoPP certificate (No.101967480) dated 09-05-2023 issued by Austrian Federal Office for safety in HealthCare (BASG). The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 3years **GMP:** The firm has also submittedOriginal legalized GMP No. DE_TH_01H_GMP_2022_0036, inspection of this manufacturer was conducted on 13-22.06.2022 and it is considered that it complies with the requirements of cGMP, Valid for three (03) years after date of issue.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **EVER VALINJECT GmbH** Oberburgau 3 4866 Unterach am Attersee **Austria.** The letter certifies that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address "Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market "**Bortezomib EVER Pharma 2.5mg/ml Solution for Injection**" in the territory of Pakistan. The letter was issued on 19.06.2023.
	Status of the applicant	Manufacturer ☒ Importer Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import Buk import and local repackaging Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 16407 Dated: 27th June 2023
	Details of fee submitted	PKR 150000/-: 23rd June 2023 Slip # 14465832
	The proposed proprietary name / brand name	**Bortezomib EVER Pharma 2.5mg/ml Solution for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API)	Each 1ml solution contains Bortezomib (as mannitol boronic ester)..... 2.5mg

	per unit	
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1's (1ml vial)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Bortezomib Ever Pharma 2.5mg/ml** MHRA approved (PL 46654/0011)
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Teva Czech Industries s.r.o (TCI) **Address:** TAPI Division, Teva Group Ostravska 305/29 Komaro, 747 70 Opava, Czech Republic.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 5ºC ± 3°C for 06 months. **Real time:** -20 ± 5°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** Brotezomib STADA 2.5 mg /1.0ml *(solution for injection)* **Manufacturer**: Thornton & Ross Ltd, UK
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

	Container closure system of the drug product	Colorless glass 6R vial, hydrolytic class type I, closed with a suitable rubber stopper and an aluminum crimp cap with a plastic flip off.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 25ºC ±2ºC **Relative Humidity:** 60% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 2ºC – 8ºC

Evaluation by PEC:

The drug product is an aqueous, clear solution for injection presented in 1.0 ml 6R vial *(readyto use)*. Its Pharmaceutical equivalence has been established with Innovator product **Valcade®** powder for solution for injection and also with competitor product **Bortezomib STADA 2.5mg/ml** solution for injection *(ready to use)*.

The drug product of the same manufacturer is approved by MHRA, UK **with a shelf life of 18 months only,** approved by TGA Australia **with a shelf life of 12 months only,** approved by EMAE **with a shelf life of 12 months only.**

In the stability studies of the drug product, significant change is observed at accelerated conditions as under.

Testing parameters	**Limits**	**At 06 month interval – Batch #**		
		C3PMM2	**C3PRM2**	**D3LPM1**
Total Impurities	≤ 4.0%	7.6%	11.4%	3.8%
Assay	95.0 to 105.0%	93.0%	88.4%	100.3%

During real time storage conditions, a slight increase in impurities has been observed but found within the limits.

As per ICH guidelines Q1 A (R2) for drug product intended for storage in a refrigerator, if significant change occurs between 3 and 6 months' testing at the accelerated storage condition, the proposed shelf life should be based on the real time data available from the long term storage condition.

Chemical & Physical in-use stability after first opening and/or dilution has been demonstratedfor 35 days at 2-8ºC protected from light, 35 days at 25ºC protected from light or 24 hours at 25ºC in normal indoor lighting conditions when stored in the original vial and/or a polypropylene syringe.

During initial scrutiny, following observations / shortcomings were observed:

Section	**Observations**	**Reply of the firm**
3.2.P.8	For the claim of 24-months shelf life of Bortezomib Ever Pharma 3.5mg/1.4ml & 2.5mg/1.0ml, please submit evidence of approval of 24 months of shelf life allowed for Bortezomib Ever Pharma 3.5mg/1.4ml & 2.5mg/1.0ml, by regulatory authority of country of origin.	Bortezomib Ever Pharma 2.5mg/ml recently got registration on 14-11-2022, with shelf life of 24 months in United Arab Emirates. Product marketing authorization approval from UAE is attached herewith. It is to inform that storage conditions for both UAE and Pakistan falls under Zone IV—A (30^{O}C ± 2 ^{O}C / RH 65% ± 5%). The stability data submitted in UAE for drug product registration is same as submitted in DRAP. We have also attached herewith stability data of accelerated condition for our refrigerated product as per room temperature conditions of Zone IV-A (30^{O}C ± 2 ^{O}C / RH 65% ± 5%)

		and it shows that our product is stable for shelf life of 24 months

Proceedings of the case:
The case was discussed in detail regarding the stability data of 24 months submitted for registration **while the shelf life of the drug product of the manufacturer in the country of origin / manufacturer (Germany) is 18 months only**.
The Board also noticed that this formulation in solution form of injection, manufactured by other manufacturer has got approval of shelf life of 24 months as well as 36 months in MHRA, UK as well as in EMAE and TGA Australia.
The Board directed to advise firm to submit approval of shelf life of 24 months of this drug product of the manufacturer from the regulatory authority of country of origin / manufacturer (Germany).

Decision: Approved with Innovator's specifications and shelf life of 18 months as per Policy for inspection of Manufacturer abroad and verification of local storage facility.
The Board directed to advise the firm to submit approval of shelf life of 24 months of this drug product of the manufacturer from the regulatory authority of country of origin / manufacturer (Germany) for consideration of stability data, in case of claim of shelf life of 24 months.

172.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0065-016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan. Address of Godown: NA Validity: 06.02.2024 Status: VALID
	Name and address of marketing authorization holder (abroad)	**EVER VALINJECT GmbH** Oberburgau 3 4866 Unterach am Attersee **Austria.**
	Name, address of manufacturer(s)	**Bulk Manufacturer, primary packaging & Product release.** EVER PHARMA Jena GmbH, Otto-Schott-StraBe 15, 07745 Jena, **Germany**. **Secondary Packaging and Labelling:** Ever Pharma Jena GmbH, Brusseler StraBe 18, 07747 Jena, **Germany.**
	Name of exporting country	**Austria**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 06th July 2023 **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 102083774) dated 21-06-2023 issued by Austrian Federal Office for safety in HealthCare (BASG). The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 3years **GMP:** The firm has also submittedOriginal legalized GMP No. DE_TH_01H_GMP_2022_0036, inspection of this manufacturer was conducted on 13-22.06.2022 and it is

		considered that it complies with the requirements of cGMP, Valid for three (03) years after date of issue.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **EVER VALINJECT GmbH** Oberburgau 3 4866 Unterach am Attersee **Austria.** The letter certifies that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address "Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market "**Bortezomib EVER Pharma 2.5mg/ml Solution for Injection**" in the territory of Pakistan. The letter was issued on 19.06.2023.
	Status of the applicant	Manufacturer ☒ Importer Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import Buk import and local repackaging Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 20966 Dated: 24th August 2023
	Details of fee submitted	PKR 150000/-: 23rd June 2023 Slip # 731600620
	The proposed proprietary name / brand name	**Bortezomib EVER Pharma 3.5mg/1.4ml Solution for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 1.4ml contains Bortezomib (as mannitol boronic ester)..... 3.5mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1's (1.4ml vial)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Bortezomib Ever Pharma 3.5mg/1.4ml** MHRA approved (PL 46654/0011)
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Teva Czech Industries s.r.o (TCI) **Address:** TAPI Division, Teva Group Ostravska 305/29 Komaro, 747 70 Opava, Czech Republic.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 5ºC ± 3°C for 06 months. **Real time:** -20 ± 5°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** Bortezomib STADA® 3.5mg/1.4ml *(Solution for injection)* **Manufacturer**: Thornton & Ross Ltd, UK
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colorless glass 6R vial, hydrolytic class type I, closed with a suitable rubber stopper and an aluminum crimp cap with a plastic flip off.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 25ºC ±2ºC **Relative Humidity:** 60% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 2ºC – 8ºC
Evaluation by PEC:		

The drug product is an aqueous, clear solution for injection presented in 1.0 ml 6R vial. Its Pharmaceutical equivalence has been established with Innovator product **Valcade®**, powder for solution for injection as well as with competitor product Bortezomib STADA 3.5mg/1.4ml.

The drug product of the same manufacturer is approved by MHRA, UK **with a shelf life of 18 months only,** approved by TGA Australia **with a shelf life of 12 months only,** approved by EMAE **with a shelf life of 12 months only.**

As per ICH guidelines Q1 A (R2) for drug product intended for storage in a refrigerator, if significant change occurs between 3 and 6 months' testing at the accelerated storage condition, the proposed shelf life should be based on the real time data available from the long term storage condition.

Chemical & Physical in-use stability after first opening and/or dilution has been demonstratedfor 35 days at 2-8ºC protected from light, 35 days at 25ºC protected from light or 24 hours at 25ºC in normal indoor lighting conditions when stored in the original vial and/or a polypropylene syringe.

During initial scrutiny, following observations / shortcomings were observed:

Section	Observations	Reply of the firm
3.2.P.8	Regarding the 24-months stability data submitted for the shelf life of Bortezomib Ever Pharma 2.5mg/1.0ml, it has been observed that the shelf life approved by EMAE for the Bortezomib vide AT/H/1124/001/DC dated 21st September 2021 is **12 months only.** Please submit updated status or reference of approval of 24 months of shelf life allowed for drug product Bortezomib Ever Pharma 2.5mg/1.0ml, by EMAE or other stringent regulatory authorities considered by WHO.	Bortezomib Ever Pharma 2.5mg/ml recently got registration on 14-11-2022, with shelf life of 24 months in United Arab Emirates. Product marketing authorization approval from UAE is attached herewith. It is to inform that storage conditions for both UAE and Pakistan falls under Zone IV—A ($30^{O}C \pm 2\ ^{O}C$ / RH 65% ± 5%). The stability data submitted in UAE for drug product registration is same as submitted in DRAP. We have also attached herewith stability data of accelerated condition for our refrigerated product as per room temperature conditions of Zone IV-A ($30^{O}C \pm 2\ ^{O}C$ / RH 65% ± 5%) and it shows that our product is stable for shelf life of 24 months

Proceedings of the case:

The case was discussed in detail regarding the stability data of 24 months submitted for registration while the shelf life of the drug product of the manufacturer in the country of origin / manufacturer (Germany) is 18 months only.

The board also noticed that this formulation in solution form of injection, manufactured by other manufacturer has got approval of shelf life of 24 months as well as 36 months in MHRA, UK as well as in EMAE and TGA Australia.

The Board directed to advise firm to submit approval of shelf life of 24 months of this drug product of the manufacturer from the regulatory authority of country of origin / manufacturer (Germany).

Decision:

Approved with Innovator's specifications and shelf life of 18 months as per Policy forinspection of Manufacturer abroad and verification of local storage facility.

The Board directed to advise firm to submit approval of shelf life of 24 months of this drug product of the manufacturer from the regulatory authority of country of origin / manufacturer (Germany) for consideration of stability data in case of claim of shelf life of 24 months.

173.	**Name, address of Applicant / Importer**	**M/s Martin Dow Limited** **Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 595 Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: Plot # 32, Sec:16 K.I.A Karachi. 1st floor, plot # 211, Sec: 23 K.I.A Karachi

		iii. Plot # 116, Sec: 15 K.I.A Karachi. Validity: 16-06-2024 Status: VALID
	Name and address of marketing authorization holder (abroad)	**DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL Sicil No: 70061 **Turkey.**
	Name, address of manufacturer(s)	**DEVA HOLDING A.S.** Organize Sanayi Bölgesi, Karaağaç Mah. Fatih bulvarı No:26, Kapaklı – TEKİRDAĞ **Turkey.**
	Name of exporting country	**Turkey**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 29th March 2023 **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2023/1057) dated 10-03-2023 issued by Turkish Medicines and Medical Device Agency. The CoPP specifies free sale status of the product in country of export along with its availability. The certifying authority arrange for periodic inspection which validity is 03 years. **GMP Certificate # TR/GMP/2022/292:** Issued on 10-11-2022 Validity: 03 years from date of issuance. Certificate confirms that drug manufacturer complies with the requirement of GMP for production of anticancer (oncological) lyophilizedinjectable vials.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL **Turkey.** The letter certifies that the drug product manufacturer in Turky authorizes **M/s Martin Dow Limited** **Address:** Plot # 37, Sector 19, Korangi Industrial Area, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **VELTEZO powder for Solution 3.5mg** in Pakistan. The letter was issued on 02.05.2023.
	Status of the applicant	Manufacturer ☒ Importer Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale Export sale Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import Buk import and local repackaging Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 13693 Dated: 01st June 2023
	Details of fee submitted	PKR 150000/-: 09th May 2023 Slip # 83749422
	The proposed proprietary name / brand name	**Veltezo 3.5mg Powder for Solution for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Bortezomib (as a mannitol boronic ester) …….3.5mg **After reconstitution:** 1 ml of solution for subcutaneous injection contains 2.5 mg bortezomib. **After reconstitution:** 1 ml of solution for intravenous injection contains 1 mg bortezomib.
	Pharmaceutical form of applied drug	Powder for Solution for Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Velcade® 3.5mg Powder for solution for injection.** MHRA approved (PLGB 00242/0707)
	For generic drugs (me-too status)	Bortezomib Pharmidea by Himont Pharma (Reg. # 093929)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** M/s Hetero Labs Limited, Unit-I **Address:** SY. #10, I.D.A., GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA STATE, **INDIA.** **GMP Validity:** 29-09-2025
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 5ºC ± 3°C for 06 months. **Real time:** -20 ± 5°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	**Name:** Velcade® 3.5mg *(powder for Solution for injection)* **Manufacturer**: Janssen-Cilag Limited, UK
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colorless glass 6R vial, hydrolytic class type I, closed with a suitable gray colored bromobutyl rubber stopper and blue colored aluminum flip off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.

Evaluation by PEC:

The details of qualitative-quantitative composition of test and reference products are as under:

-

Name of Ingredients	Reference Product	Test Product
	VELCADE ® mg/ml	**Veltezo ® mgml**
Bortezomib	1.0	1.0
D-mannitol	10.0	10.0
Tetra Butyl alcohol*	+	-
Acetone*	-	+
WFI*	Q.S	Q.S
Total	1ml	1ml

**not included in finished product, removed by sublimation during process.*

In order to protect the bulk product from oxidation, tetra-butyl alcohol was used as an organic solvent in the reference product. For this reason, development studies were started with tatra-

butyl alcohol. However, due to the impurity caused by the esterification reaction between tera-butyl alcohol and boronic acid, it was decided to use ketone group ICH Class II organic solvents. In the final formulation, acetone was used as the organic solvent. Intravenous in-use stability after first opening and/or dilution has been demonstrated for 08 hours at 25°C ± 2°C/ 60% ±5RH protected from light.
Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility

Item No. 04: (CONTRACT MANUFACTURING APPLICATIONS AS PER DECISION OF 173RD MEETING OF AUTHORITY)

174.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Well & Well Pharma (Pvt) Ltd. (DML # 000687) Plot No.7 Street S-8 National Industrial Zone RCCI Rawat.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Vision Pharmaceuticals (DML # 000517) Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2278 (dated: 24-01-2023)
	Details of fee submitted	PKR 75,000/-: dated: 18-11-2022 (Invoice # 241860570976)
	The proposed proprietary name / brand name	Cipnolone 200mg/100ml infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml of solution in glass vial contains: Ciprofloxacin (as Lactate) .....200 mg
	Pharmaceutical form of applied drug	Sterile solution for IV infusion
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved (PL04515/0208)
	For generic drugs (me-too status)	Novidat by M/s Sami
	Section Approval Letter from Licensing Division of DRAP	Renewal Letter of DML contains Liquid Injectable Vial SVP (General). Issuance date: 07-06-2021
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 12-01-2025 **Giver:** GMP certificate valid up to 07-12-2023

	Name and address of API manufacturer.	**Name:** M/s Shangyu Jingxin Pharmaceuticals Co. Ltd. **Address:** No. 31, Weisan Road, Hangzhou Bay, Shangyu Economic and technological development area. China. **GMP Validity:** 29-11-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Novidat 100ml infusion **Manufacturer:** M/s Sami Pharmaceuticals **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Shangyu Jingxin Pharmaceuticals Co. Ltd. **Address:** No. 31, Weisan Road, Hangzhou Bay, Shangyu Economic and technological development area. China.		
API Lot No.	DK12-2110011-A		
Description of Pack (Container closure system)	Clear Solution of Ciprofloxacin as lactate filled in glass bottles.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	C22071	D22002	D22003
Batch Size	1500 Bottles	1500 Bottles	1500 Bottles

Manufacturing Date	05/2022	06/2022	06/2022
Date of Initiation	14-06-2022	16-06-2022	16-06-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 50kg **Clearance date:** 28-04-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Decision: Approved.

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

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

175.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s World Biz Pharmaceuticals Company (Pvt) Ltd. (DML # 000942) Plot No. 340, Multan Industrial Estate, Multan.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s GT Pharma (Pvt) Ltd. (DML # 000829) 713 Sundar Industrial Estate Lahore.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1972 (dated: 20-01-2023)
	Details of fee submitted	PKR 75,000/-: dated: 31-10-2022

		(Invoice # 38747774840)
	The proposed proprietary name / brand name	UP-D3 Injection 5mg/1ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of injection contains: cholecalciferol (Vitamin D3)..... 5 mg (200,000 IU)
	Pharmaceutical form of applied drug	Sterile solution for IM injection
	Pharmacotherapeutic Group of (API)	Vitamin D_3
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1 x 1
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ASNM France approved (CIS: 6 659 708 3)
	For generic drugs (me-too status)	ED3 Injection by GT Pharma
	Section Approval Letter from Licensing Division of DRAP	Renewal Letter of DML contains Liquid Injectable ampoules & Vial SVP (General). Issuance date: 10-03-2022
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 26-11-2026
	Name and address of API manufacturer.	**Name:** M/s Fermenta Biotech Limited **Address:** Plot # Z-109 B & C, SEZ-II, DAHEJ. TAL – VAGRA, City: Dahej, Dist. Bharuch, Gujrat, India. **GMP Validity:** 17-06-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 5˚C ± 3˚C for 36 months **Accelerated:** 25˚C ± 2˚C / 60% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Indrop D **Manufacturer:** M/s Neutra **Testing parameters:** Innovator's Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Fermenta Biotech Limited **Address:** Plot # Z-109 B & C, SEZ-II, DAHEJ. TAL – VAGRA, City: Dahej, Dist. Bharuch, Gujrat, India.		
API Lot No.	CLC0421304		
Description of Pack (Container closure system)	Type I printed glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	ED065	ED066	ED067
Batch Size	46260 Ampoules	46260 Ampoules	46260 Ampoules
Manufacturing Date	09-2020	09/2020	06/2022
Date of Initiation	03-11-2020	19-11-2020	01-12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 3kg **Clearance date:** 17-06-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed analysis on UV spectroscopy
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status

1.6.5	Please submit GMP Certificate of API manufacturer issued by the regulatory authority of country of origin and should be in force till date.	Submitted	
1.3.4	Please submit fresh/valid GMP certificate of GT Pharma or inspection report conducted within last 03 years to confirm the GMPcompliance status of the manufacturing facility. Please submit GMP certificate of WorldBiz Pharmaceuticals to confirm the validity of the Drug Manufacturing License.	Submitted	

Decision: Approved with Innovator Specifications.

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

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

176.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Zamko Pharmaceuticals (Pvt) Ltd., (DML # 000890) Plot No. 641-A, Sunder Industrial Estate, Lahore.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s GT Pharma (Pvt) Ltd. (DML # 000829) 713 Sundar Industrial Estate Lahore.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1971 (dated: 20-01-2023)
	Details of fee submitted	PKR 75,000/-: dated: 29-04-2022 (Invoice # 9706450368)
	The proposed proprietary name / brand name	ZEM-D3 Injection 5mg/1ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of injection contains: cholecalciferol (Vitamin D3)..... 5 mg (200,000 IU)
	Pharmaceutical form of applied drug	Sterile solution for IM injection
	Pharmacotherapeutic Group of (API)	Vitamin D_3
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1 x 1
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ASNM France approved (CIS: 6 659 708 3)
	For generic drugs (me-too status)	ED3 Injection by GT Pharma
	Section Approval Letter from Licensing Division of DRAP	Renewal Letter of DML contains Liquid Injectable ampoules & Vial SVP (General). Issuance date: 10-03-2022

	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 26-11-2026
	Name and address of API manufacturer.	**Name:** M/s Fermenta Biotech Limited **Address:** Plot # Z-109 B & C, SEZ-II, DAHEJ. TAL – VAGRA, City: Dahej, Dist. Bharuch, Gujrat, India. **GMP Validity:** 17-06-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 5°C ± 3°C for 36 months **Accelerated:** 25°C ± 2°C / 60% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Indrop D **Manufacturer:** M/s Neutra **Testing parameters:** Innovator's Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Fermenta Biotech Limited **Address:** Plot # Z-109 B & C, SEZ-II, DAHEJ. TAL – VAGRA, City: Dahej, Dist. Bharuch, Gujrat, India.
API Lot No.	CLC0421304
Description of Pack (Container closure system)	Type I printed glass ampoules
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)

Batch No.	ED065	ED066	ED067
Batch Size	46260 Ampoules	46260 Ampoules	46260 Ampoules
Manufacturing Date	09-2020	09/2020	06/2022
Date of Initiation	03-11-2020	19-11-2020	01-12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 17-06-2020 **Clearance date:** 3 kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed analysis on UV spectroscopy
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP Certificate of API manufacturer issued by the regulatory authority of country of origin and should be in force till date.	Submitted
1.3.4	Please submit fresh/valid GMP certificate of GT Pharma or inspection report conducted within last 03 years to confirm the GMPcompliance status of the manufacturing facility.	Submitted
3.2.P.8	Please provide clearance documents from DRAP for procurementof API.	Submitted

Decision: Approved with Innovator Specifications.

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

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

177.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt) Ltd., (DML # 000648) 8- Pharma City, 30-km, Multan Road, Lahore.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s GT Pharma (Pvt) Ltd. (DML # 000829) 713 Sundar Industrial Estate Lahore.**
	Status of the applicant	Manufacturer Importer

		☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1974 (dated: 20-01-2023)
	Details of fee submitted	PKR 75,000/-: dated: 17-11-2022 (Invoice # 15987188)
	The proposed proprietary name / brand name	Apti-3 Injection 5mg/1ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of injection contains: cholecalciferol (Vitamin D3)..... 5 mg (200,000 IU)
	Pharmaceutical form of applied drug	Sterile solution for IM injection
	Pharmacotherapeutic Group of (API)	Vitamin D_3
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1 x 1
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ASNM France approved (CIS: 6 659 708 3)
	For generic drugs (me-too status)	ED3 Injection by GT Pharma
	Section Approval Letter from Licensing Division of DRAP	Renewal Letter of DML contains Liquid Injectable ampoules & Vial SVP (General). Issuance date: 10-03-2022
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 12-10-2023
	Name and address of API manufacturer.	**Name:** M/s Fermenta Biotech Limited **Address:** Plot # Z-109 B & C, SEZ-II, DAHEJ. TAL – VAGRA, City: Dahej, Dist. Bharuch, Gujrat, India. **GMP Validity:** 17-06-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 5˚C ± 3˚C for 36 months **Accelerated:** 25˚C ± 2˚C / 60% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Indrop D **Manufacturer:** M/s Neutra **Testing parameters:** Innovator's Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Fermenta Biotech Limited **Address:** Plot # Z-109 B & C, SEZ-II, DAHEJ. TAL – VAGRA, City: Dahej, Dist. Bharuch, Gujrat, India.		
API Lot No.	CLC0421304		
Description of Pack (Container closure system)	Type I printed glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	ED065	ED066	ED067
Batch Size	46260 Ampoules	46260 Ampoules	46260 Ampoules
Manufacturing Date	09-2020	09/2020	06/2022
Date of Initiation	03-11-2020	19-11-2020	01-12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.

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

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP Certificate of API manufacturer issued by the regulatory authority of country of origin and should be in force till date.	Submitted
1.3.4	Please submit fresh/valid GMP certificate of GT Pharma or inspection report conducted within last 03 years to confirm the GMP compliance status of the manufacturing facility. Please submit GMP certificate of Aptcure to confirm the validity ofthe Drug Manufacturing License.	Submitted
3.2.P.8	Please provide clearance documents from DRAP for procurementof API.	Submitted

Decision: Approved with Innovator Specifications.

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

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

178.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt) Ltd., (DML # 000648) 8- Pharma City, 30-km, Multan Road, Lahore.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s GT Pharma (Pvt) Ltd. (DML # 000829) 713 Sundar Industrial Estate Lahore.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1973 (dated: 20-01-2023)
	Details of fee submitted	PKR 75,000/-: dated: 17-11-2022 (Invoice # 9898905766)
	The proposed proprietary name / brand name	APOLAC Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of ampoule contains: Ketorolac tromethamine .....30 mg
	Pharmaceutical form of applied drug	Solution for injection IM/IV
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product	USP Specification

	specifications	
	Proposed Pack size	5 x 1
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved product by Hospira
	For generic drugs (me-too status)	Ketrodil Injection 30 mg
	Section Approval Letter from Licensing Division of DRAP	Renewal Letter of DML contains Liquid Injectable ampoules & Vial SVP (General). Issuance date: 10-03-2022
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 12-10-2023
	Name and address of API manufacturer.	**Name:** M/s Saurav Chemicals Limited **Address:** Village Bhagwanpura, Barwala Road, Derabassi, District Sahibzada Ajit Singh (SAS) Nagar, Punjab, India. **GMP Validity:** 25-06-2023
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Toradol **Manufacturer:** M/s Barrett **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.
STABILITY STUDY DATA		
Manufacturer of API	**Name:** M/s Saurav Chemicals Limited	

	Address: Village Bhagwanpura, Barwala Road, Derabassi, District Sahibzada Ajit Singh (SAS) Nagar, Punjab, India.		
API Lot No.	KTM180018		
Description of Pack (Container closure system)	Type I printed glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24, 36 (Months)		
Batch No.	TK001	TK002	TK003
Batch Size	30000 Ampoules	30000 Ampoules	30000 Ampoules
Manufacturing Date	07-2019	11/2019	08/2020
Date of Initiation	09-08-2019	13-12-2019	03-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 3.5 kg **Clearance date:** 09-07-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed analysis on UV spectroscopy
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP Certificate of API manufacturer issued by the regulatory authority of country of origin and should be in force till date.	Submitted
1.3.4	Please submit fresh/valid GMP certificate of GT Pharma or inspection report conducted within last 03 years to confirm the GMP compliance status of the manufacturing facility. Please submit GMP certificate of Aptcure to confirm thevalidity of the Drug Manufacturing License.	Submitted
3.2.P.8	Please provide clearance documents from DRAP for procurement of API.	Submitted

Decision: Approved. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
179.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt) Ltd., (DML # 000648)** **8- Pharma City, 30-km, Multan Road, Lahore.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s GT Pharma (Pvt) Ltd. (DML # 000829)** **713 Sundar Industrial Estate Lahore.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7165 (dated: 13-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 17-11-2022 (Invoice # 56360541)
	The proposed proprietary name / brand name	Macxee Injection 500mcg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of ampoule contains: Mecobalamin.....500 mcg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Cyanocobalamin and analogues
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methycobal ® injection by Eisai Japan
	For generic drugs (me-too status)	Beacom injection by GT Pharma
	Section Approval Letter from Licensing Division of DRAP	Renewal Letter of DML contains Liquid Injectable ampoules & Vial SVP (General). Issuance date: 10-03-2022
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 12-10-2023
	Name and address of API manufacturer.	**Name:** M/s Mahima Life Sciences Pvt. Ltd. **Address:** BST. Road, Ganaur – 131101 Sonepat, Haryana, India. **GMP Validity:** 12-09-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 48 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Methycobal Injection **Manufacturer:** M/s Hilton **Testing parameters:** Innovator's Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s Mahima Life Sciences Pvt. Ltd. **Address:** BST. Road, Ganaur – 131101 Sonepat, Haryana, India. **GMP Validity:** 12-09-2022		
API Lot No.	MLMCB-320619		
Description of Pack (Container closure system)	Type I printed amber glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24, 36 (Months)		
Batch No.	MC002	MC003	MC004
Batch Size	61500 Ampoules	61500 Ampoules	61500 Ampoules
Manufacturing Date	11-2019	08-2020	12-2021
Date of Initiation	06-12-2019	28-08-2020	12-01-2022
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 0.5KG **Clearance date:** 26-06-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed analysis on UV spectroscopy
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP Certificate of API manufacturer issued by the regulatory authority of country of origin and should be in force till date.	Submitted
1.3.4	Please submit fresh/valid GMP certificate of GT Pharma or inspection report conducted within last 03 years to confirm the GMP compliance status of the manufacturing facility. Please submit GMP certificate of World Biz Pharmaceuticals to confirm the validity of the Drug Manufacturing License.	Submitted
3.2.P.2	Please justify with documented evidence the use of overage of 5% for mecobalamin in the formulation (715mcg) instead of exact amount 500mcg.	Submitted
3.2.P.8	Please provide clearance documents from DRAP for procurement of API.	

Decision: Approved with Innovator Specifications.

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

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

180.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals (DML # 000900) Plot No. 84/1 Block-B Phase V Industrial Estate Hattar.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Aulton Pharmaceuticals. (DML # 000828) Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 476 (dated: 05-01-2023)
	Details of fee submitted	PKR 75,000/-: dated: 03-01-2023 (Invoice # 080289600805)
	The proposed proprietary name / brand name	Athicef 200mg/5ml Oral Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime trihydrate equivalent to Cefixime .....200 mg
	Pharmaceutical form of applied drug	Oral Powder for reconstitution
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved product by Belcher
	For generic drugs (me-too status)	Caricef by Sami Pharma
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board in its 252nd meeting held on 15th March 2017 approved grant of additional section **Capsule (Cephalosporin) Section.**
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 10-12-2023
	Name and address of API manufacturer.	**Cefixime (Micronized)** **Name:** M/s Citi Pharma (Pvt) Ltd. **Address:** 3.5-Km Head Balloki Road Phool Nagar Kasur **GMP Validity:** 02-03-2026
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions:

		Real time: 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Cefspan Suspension 200mg/5ml **Manufacturer:** M/s Barrett **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Cefixime (Micronized)** **Name:** M/s Citi Pharma (Pvt) Ltd. **Address:** 3.5-Km Head Balloki Road Phool Nagar Kasur		
API Lot No.	CFM2106071		
Description of Pack (Container closure system)	Type I printed glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24, 36 (Months)		
Batch No.	C217	C256	C295
Batch Size	3000 Bottles	3000 Bottles	3000 Bottles
Manufacturing Date	10-2021	12-2021	01-2022
Date of Initiation	08-10-2021	20-12-2021	05-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 15kg Locally procured from Citi pharma
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit	Submitted

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

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	For the manufacturing of drug product in facility of Oral dry powder suspension (Cephalosporin) of Aulton Pharma, please submit section approval letter issued by Licensing Division DRAP.	Submitted
	Please submit evidence for GMP compliance status of Athan Pharma.	Submitted

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

181.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals (DML # 000900)** **Plot No. 84/1 Block-B Phase V Industrial Estate Hattar.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s Aulton Pharmaceuticals. (DML # 000828) Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6414 (dated: 07-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 09-02-2023 (Invoice # 81452254803)
	The proposed proprietary name / brand name	Ceftrix 250 mg Injection IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for reconstitution)* Ceftriaxone Sodium equivalent to Ceftriaxone .....250 mg
	Pharmaceutical form of applied drug	Sterile Powder for reconstitution for IM injection.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved product by Qilu

	For generic drugs (me-too status)	Oxidil by Sami Pharma
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board in its 252nd meeting held on 15th March 2017 approved grant of additional section **Sterile Powder vials (Cephalosporin) Section.**
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 10-12-2023
	Name and address of API manufacturer.	**Name:** M/s Henan Kangda Pharmaceutical Co. Ltd. **Address:** No. 66 Jing Wu Road, Xiang Cheng City, China **GMP Validity:** 01-12-2023
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Oxidil Injection 250mg **Manufacturer:** M/s Sami **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Henan Kangda Pharmaceutical Co. Ltd. **Address:** No. 66 Jing Wu Road, Xiang Cheng City, China
API Lot No.	YK20021909
Description of Pack (Container closure system)	Sterile white to off white / yellowish crystalline powder filled in transparent type II glass vials with grey rubber stopper with a flip-off seal.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24, 36 (Months)		
Batch No.	C134	C196	C208
Batch Size	10000 vials	10000 vials	10000 vials
Manufacturing Date	05-2020	07-2020	10-2020
Date of Initiation	01-06-2020	01-08-2020	02-11-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 79.5kg **Clearance date:** 10-03-2020 **Invoice#** YK19093034
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be in force till date.	Submitted
1.3.4	For the manufacturing of drug product in facility of Vials of Sterile Powder for injection (Cephalosporin) of Aulton Pharma, please submit section approval letter issued by Licensing Division DRAP. Please submit evidence for GMP compliance status of Athan Pharma.	Submitted
3.2.P.8	Please submit source and details of registration of solvent usedfor dilution for IM injection. Please submit datasheets of stability studies of solution after reconstitution.	Submitted

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
182.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals (DML # 000900)** **Plot No. 84/1 Block-B Phase V Industrial Estate Hattar.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s Aulton Pharmaceuticals. (DML # 000828) Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6415 (dated: 07-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 15-02-2023 (Invoice # 17075616)
	The proposed proprietary name / brand name	Ceftrix 500 mg Injection IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for reconstitution)* Ceftriaxone Sodium equivalent to Ceftriaxone .....500 mg
	Pharmaceutical form of applied drug	Sterile Powder for reconstitution for IM injection.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved product by Qilu
	For generic drugs (me-too status)	Oxidil by Sami Pharma
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board in its 252nd meeting held on 15th March 2017 approved grant of additional section **Sterile Powder vials (Cephalosporin) Section.**
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 10-12-2023
	Name and address of API manufacturer.	**Name:** M/s Henan Kangda Pharmaceutical Co. Ltd. **Address:** No. 66 Jing Wu Road, Xiang Cheng City, China **GMP Validity:** 01-12-2023
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Rocephin Injection 500mg **Manufacturer:** M/s Roche **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s Henan Kangda Pharmaceutical Co. Ltd. **Address:** No. 66 Jing Wu Road, Xiang Cheng City, China		
API Lot No.	YK20021909		
Description of Pack (Container closure system)	Sterile white to off white / yellowish crystalline powder filled in transparent type II glass vials with grey rubber stopper with a flip-off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24, 36 (Months)		
Batch No.	C133	C195	C209
Batch Size	10000 vials	10000 vials	10000 vials
Manufacturing Date	05-2020	07-2020	10-2020
Date of Initiation	01-06-2020	01-08-2020	02-11-2020
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 79.5kg **Clearance date:** 10-03-2020 **Invoice#** YK19093034
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be in force till date.	Submitted
1.3.4	For the manufacturing of drug product in facility of Vials of Sterile Powder for injection (Cephalosporin) of Aulton Pharma, please submit section approval letter issued by Licensing Division DRAP. Please submit evidence for GMP compliance status of Athan Pharma.	Submitted

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

183.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals (DML # 000900) Plot No. 84/1 Block-B Phase V Industrial Estate Hattar.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Aulton Pharmaceuticals. (DML # 000828) Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical	Domestic sale

	product	Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6416 (dated: 07-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 15-02-2023 (Invoice # 17075616)
	The proposed proprietary name / brand name	Ceftrix 1G Injection IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for reconstitution)* Ceftriaxone Sodium equivalent to Ceftriaxone .....1000 mg
	Pharmaceutical form of applied drug	Sterile Powder for reconstitution for IM injection.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved product by Qilu
	For generic drugs (me-too status)	Oxidil by Sami Pharma
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board in its 252nd meeting held on 15th March 2017 approved grant of additional section **Sterile Powder vials (Cephalosporin) Section.**
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 10-12-2023
	Name and address of API manufacturer.	**Name:** M/s Henan Kangda Pharmaceutical Co. Ltd. **Address:** No. 66 Jing Wu Road, Xiang Cheng City, China **GMP Validity:** 01-12-2023
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Rocephin Injection 1G **Manufacturer:** M/s Roche **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Henan Kangda Pharmaceutical Co. Ltd. **Address:** No. 66 Jing Wu Road, Xiang Cheng City, China		
API Lot No.	YK20021909		
Description of Pack (Container closure system)	Sterile white to off white / yellowish crystalline powder filled in transparent type II glass vials with grey rubber stopper with a flip-off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24, 36 (Months)		
Batch No.	C135	C194	C207
Batch Size	10000 vials	10000 vials	10000 vials
Manufacturing Date	05-2020	07-2020	10-2020
Date of Initiation	01-06-2020	01-08-2020	02-11-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 79.5kg **Clearance date:** 10-03-2020 **Invoice#** YK19093034
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	Please submit GMP certificate of API manufacturer issued by regulatory authority of country of origin and should be in force till date.	Submitted
1.3.4	For the manufacturing of drug product in facility of Vials of Sterile Powder for injection (Cephalosporin) of Aulton Pharma, please submit section approval letter issued by Licensing Division DRAP. Please submit evidence for GMP compliance status of Athan Pharma.	Submitted

Decision: Approved.

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

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

184.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals (DML # 000882) Plot 23 & 24, S-1, RCCI Industrial estate, Rawat.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s WeatherFolds Pharmaceuticals (DML # 000644) Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1365 (dated: 16-01-2023)
	Details of fee submitted	PKR 75,000/-: dated: 18-05-2022 (Invoice # 5995709623)
	The proposed proprietary name / brand name	Empaa-M 12.5/500 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each immediate release film coated tablet contains: Metformin HCl ..... 500 mg Empagliflozin 12.5mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	2 x 7s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMAE approved formulation **Synjardy ®**

	For generic drugs (me-too status)	Xenglu-Met 12.5/500 tablet by Hilton
	Section Approval Letter from Licensing Division of DRAP	Approval by Central Licensing Board in its 222nd meeting held on 04th March 2010
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 27-10-2025
	Name and address of API manufacturer.	**Empagliflozin** **Name:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning, China **GMP Validity:** 25-05-2024 **Metformin** **Name:** M/s AARTI Drugs Limited. **Address**: Mahendra Industrial Estate, Plot # 109-D, Road No. 29, Sion (East) Mumbai, India. **GMP validity :** 17-02-2025
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	**Empagliflozin** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 24 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months **Metformin HCl** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Synjardy 12.5/500 Tablet **Manufacturer:** M/s Boehringer Ingelheim **Testing parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system

		suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin** **Name:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd. **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning, China **GMP Validity:** 25-05-2024 **Metformin HCl** **Name:** M/s AARTI Drugs Limited. **Address**: Mahendra Industrial Estate, Plot # 109-D, Road No. 29, Sion (East) Mumbai, India. **GMP validity :** 17-02-2025		
API Lot No.	**Empagliflozin**	**Metformin HCl**	
	E-20190920-D02-E06-01	MEF/19102354	
Description of Pack (Container closure system)	14 in ALU-ALU blister packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	770	771	772
Batch Size	14000 tablets	14000 tablets	14000 tablets
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	10-2020	10-2020	10-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	*Material Loan from welwink* **Empagliflozin** **Quantity:** 0.34 kg **Invoice #** HN200103-F **Dated:** 03-01-2020 **Metformin HCl** **Quantity:** 15 kg **Invoice #** EXP/2932/19-20 **Dated:** 09-01-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software	Submitted

	21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	Please submit evidence for GMP compliance status of WezenPharma.	Submitted

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

185.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Nicholas Pharmaceuticals (DML # 000886)** **Plot 34, Street No. SS-2, National Industrial Zone, Rawat.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s Caliph Pharmaceuticals (Pvt) Ltd. (DML # 000748)** **Plot No. 17 Industrial Estate Risalpur.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3119 (dated: 02-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 01-02-2023 (Invoice # 29587530592)
	The proposed proprietary name / brand name	Terviza 1% Cream
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Terbinafine HCl..... 10 mg
	Pharmaceutical form of applied drug	Topical Cream
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	JP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation **Lamisil® 1%**
	For generic drugs (me-too status)	Lamisil by GSK

	Section Approval Letter from Licensing Division of DRAP	Cream/Ointment/Lotion Section (General), Approval by Central Licensing Board in its 267th meeting held on 31st December 2018.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 01-03-2023
	Name and address of API manufacturer.	**Name:** M/s Saptagir Laboratories Pvt. Ltd. **Address:** SYNO PARTS OF 27,46 AND 50 TO 56, 502247, ANANTHASAGAR (V), CHEGUNTA(M), MEDAK (DIST.) India. **GMP Validity:** 20-02-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Lamisil 1% Cream **Manufacturer:** M/s GSK **Testing parameters:** JP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s Saptagir Laboratories Pvt. Ltd. **Address:** SYNO PARTS OF 27,46 AND 50 TO 56, 502247, ANANTHASAGAR (V), CHEGUNTA(M), MEDAK (DIST.) India.
API Lot No.	TH0180421
Description of Pack (Container closure system)	Collapsible Aluminium tube
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T001	T001	T001
Batch Size	400 tubes	400 tubes	400 tubes
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 100 kg **Invoice #** 2122/SL/032 **Dated:** 05-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	Please submit evidence for GMP compliance status of Nicholas Pharma. Please submit GMP certificate of Caliph Pharma **OR** inspection report conducted within last 03 years for confirmation of GMP compliance status of the Cream/Ointment/Lotion section of manufacturing facility	Submitted
1.6.5	Please submit GMP Certificate of API supplier which should bein force till date.	Submitted

Decision: Approved.

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

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

186.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions (DML # 000951) Kala Wala Stop, 20-km, Lahore Jaranwala Road, Lahore.**

	Contract Acceptor **Name, address of Manufacturing site.**	**M/s WeatherFolds Pharmaceuticals** **(DML # 000644)** **Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4217 (dated: 14-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 10-11-2022 (Invoice # 9290012067)
	The proposed proprietary name / brand name	Vonp-AS 10/100 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Aspirin as Enteric Coated Tablet..... 100 mg **With drug coating of** Vonoprazan as fumarate as immediate release layer …… 10 mg
	Pharmaceutical form of applied drug	Yellow color round in shape, film coated tablets (Aspirin delayed release and Vonoprazan immediate release tablets)
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA approved **Cabpirin ®** by Otsuka.
	For generic drugs (me-too status)	N/A
	Section Approval Letter from Licensing Division of DRAP	Tablet (General) Section, Approval by Central Licensing Board in its 222nd meeting held on 04th March 2010.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 27-10-2025 **Giver:** ***not provided***
	Name and address of API manufacturer.	**Vonprazan** **Name:** M/s AMI Life Sciences **Address:** Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. **GMP Validity:** expired in year 2022 **Aspirin** **Name:** M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. **Address:** Yuquan Road, Huayin City, Shanxi Province, China. **GMP Validity:** expired in year 2022
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	**Vonoprazan** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 12 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months **Aspirin** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 48 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Cabpirin 100/10 Tablet **Manufacturer:** M/s Otsuka **Testing parameters:** Innovator Specifications **Batch #** 521559
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA		
Manufacturer of API	**Vonprazan** **Name:** M/s AMI Life Sciences **Address:** Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. **GMP Validity:** expired in year 2022 **Aspirin** **Name:** M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. **Address:** Yuquan Road, Huayin City, Shanxi Province, China. **GMP Validity:** expired in year 2022	
API Lot No.	**Vonoprazan fumarate**	**Aspirin**

	Not provided		Not provided
Description of Pack (Container closure system)	30 in ALU-ALU Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	21-09-2021	21-09-2021	21-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 100 kg **Invoice #** 2122/SL/032 **Dated:** 05-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations
1.3.4	Please submit evidence for GMP compliance status of Wallace Pharma.
1.6.5	Please submit GMP Certificate of API suppliers for Vonoprazan and Aspirin which should be in force till date.
3.2.P.2	Please justify that why drug coating method of tablet has been chosen instead of bilayer tablets which is a recommended method for tablet formulation for combination of two incompatible APIs? Please submit evidence that innovator brand **"Cabpirin combination tablet"** by Otsuka, Japan, is a vonoprazan coated tablet and not a bilayer tablet of two APIs. Since Vonoprazan has a bitter taste, what steps have been taken to mask the bitter taste of API coating? Please clarify whether in process test for Vonoprazan containing drug coating

	suspension has been performed? If yes, then submit validation data as well as anaylytical testing parameters with reference of testing. Please submit data regarding weight gain of enteric coated tablet of Aspirin before and after spraying the drug coating suspension containing Vonoprazan. Please submit documented evidence that the coating machine used for drug coating suspension contains Human machine interface (HMI) to control the opening and closing of the exhaust during coating time.	
3.2.P.5	Please submit detailed procedure regarding disintegration time requirement for drug coating of vonoprazan and then disintegrating time of enteric coated aspirin. Please submit detailed dissolution procedure along with reference.	

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

187.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals (DML # 000574) Plot No 3 Block –A Phase-I-II Industrial Estate Hattar.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s WeatherFolds Pharmaceuticals (DML # 000644) Plot No. 62/2 Phase-II Industrial Estate Hattar.**
	Status of the applicant	Manufacturer Importer ☒ Is involved in none of the above (contract giver)
	Status of application	New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic sale Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3927 (dated: 10-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 09-01-2023 (Invoice # 4704293740)
	The proposed proprietary name / brand name	Vonp-AS 10/100 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Aspirin as Enteric Coated Tablet..... 100 mg **With drug coating of** Vonoprazan as fumarate as immediate release layer …… 10 mg
	Pharmaceutical form of applied drug	Yellow colour round in shape, film coated tablets (Aspirin delayed release and Vonoprazan immediate release tablets)
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA approved **Cabpirin ®** by Otsuka.
	For generic drugs (me-too status)	N/A
	Section Approval Letter from	Tablet (General) Section, Approval by Central

	Licensing Division of DRAP	Licensing Board in its 222nd meeting held on 04th March 2010.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 27-10-2025 **Giver:** ***not provided***
	Name and address of API manufacturer.	**Vonprazan** **Name:** M/s AMI Life Sciences **Address:** Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. **GMP Validity:** expired in year 2022 **Aspirin** **Name:** M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. **Address:** Yuquan Road, Huayin City, Shanxi Province, China. **GMP Validity:** expired in year 2022
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	**Vonoprazan** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 12 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months **Aspirin** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 48 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Cabpirin 100/10 Tablet **Manufacturer:** M/s Otsuka **Testing parameters:** Innovator Specifications **Batch #** 521559
	Analytical method	Firm has submitted report of validation of analytical

	validation/verification of product	method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Vonprazan** **Name:** M/s AMI Life Sciences **Address:** Block No.82/B, ECP Road, At & Post. Karakhadi-391450 Taluka: Padra Dist.: Vadodara Gujarat, INDIA. **GMP Validity:** expired in year 2022 **Aspirin** **Name:** M/s JQC (HUAYIN) Pharmaceutical Co. Ltd. **Address:** Yuquan Road, Huayin City, Shanxi Province, China. **GMP Validity:** expired in year 2022

API Lot No.	**Vonoprazan fumarate**	**Aspirin**
	Not provided	Not provided

Description of Pack (Container closure system)	30 in ALU-ALU Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	21-09-2021	21-09-2021	21-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 100 kg **Invoice #** 2122/SL/032 **Dated:** 05-08-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks of the Evaluator:

Section	Observations
1.3.4	• Please submit evidence for GMP compliance status of Wallace Pharma.
1.6.5	• Please submit GMP Certificate of API suppliers for Vonoprazan and Aspirin which should be in force till date.
3.2.P.2	• Please justify that why drug coating method of tablet has been chosen instead of bilayer tablets which is a recommended method for tablet formulation for combination of two incompatible APIs? • Please submit evidence that innovator brand **"Cabpirin combination tablet"** by Otsuka, Japan, is a vonoprazan coated tablet and not a bilayer tablet of two APIs. • Since Vonoprazan has a bitter taste, what steps have been taken to mask the bitter taste of API coating? • Please clarify whether in process test for Vonoprazan containing drug coating suspension has been performed? If yes, then submit validation data as well as anaylytical testing parameters with reference of testing. • Please submit data regarding weight gain of enteric coated tablet of Aspirin before and after spraying the drug coating suspension containing Vonoprazan. • Please submit documented evidence that the coating machine used for drug coating suspension contains Human machine interface (HMI) to control the opening and closing of the exhaust during coating time.
3.2.P.5	• Please submit detailed procedure regarding disintegration time requirement for drug coating of vonoprazan and then disintegrating time of enteric coated aspirin. • Please submit detailed dissolution procedure along with reference.

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

188.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma (Pvt) Ltd. (DML # 000688)** **27-Sundar Industrial Estate Sundar Raiwind Road Lahore.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s Genix Pharma (Pvt) Ltd. (DML # 000351)** **44-45/B Korangi Creek Raod Karachi**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20376 (dated: 05-08-2022)
	Details of fee submitted	PKR 75,000/-: dated: 04-07-2022 (Invoice # 475885685)
	The proposed proprietary name / brand name	Omzole Delayed Release Capsule 20 mg
	Strength / concentration of drug of	Each delayed released capsule contains:

	Active Pharmaceutical ingredient (API) per unit	Omeprazole enteric coated pellets equivalent to Omeprazole ..... 20 mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule containing enteric coated pellets.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 30's, 50's, 60's, 100's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Losec®.
	For generic drugs (me-too status)	Risek 20 mg by Getz
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board in its 282nd meeting held on 31st August 2021 approved the amendment in Tablet (General) Section of the firm.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 12-06-2025 **Giver:** GMP certificate valid up to : 01-02-2025
	Name and address of API manufacturer.	**Omeprazole E.C Pellets 10%** **Name:** Metrochem API Private Limited **Address:** Plot # D-69, Phase I, IDA Jeedimetla, Hyderabad, India. **GMP Validity:** 07-07-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Capsule Risek 20mg **Manufacturer:** M/s Getz

		Testing parameters: USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Omeprazole E.C Pellets 10%** **Name:** Metrochem API Private Limited **Address:** Plot # D-69, Phase I, IDA Jeedimetla, Hyderabad, India.		
API Lot No.	OMP/P/2/2021040658		
Description of Pack (Container closure system)	Capsule 20mg packed in ALU-ALU blister, further packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	035C080	036C080	037C080
Batch Size	300000 Capsules	300,000 Capsules	300000 Capsules
Manufacturing Date	11-2019	12-2019	03-2020
Date of Initiation	06-12-2019	25-01-2020	27-03-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 200 kg **Invoice #** BE/17/047 **Dated:** 11-07-2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit evidence for GMP compliance status of Daneen Pharma.	All documents

	• Please submit GMP certificate of Genix Pharma which should be valid till date **OR** submit inspection report of the firm conducted within last three (03) years for confirmation of GMP compliance status of manufacturing facility for Capsule (General) Section. • Letter issued by Licensing Division DRAP for Approval of manufacturing facility of Tablet (General) Section by Central Licensing Board. • Please submit Contract agreement between two parties for the manufacturing of **Omzole Capsule 20 mg.**	submitted by firm.	
1.6.5	• Please submit GMP Certificate of API suppliers for Vonoprazan and Aspirin which should be in force till date.	Submitted	
3.2.P.8	• Please submit clearance document from DRAP for procurement of API.	Submitted	

Decision: Approved.

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

189.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma (Pvt) Ltd. (DML # 000688) 27-Sundar Industrial Estate Sundar Raiwind Road Lahore.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Genix Pharma (Pvt) Ltd. (DML # 000351) 44-45/B Korangi Creek Raod Karachi**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23277 (dated: 17-08-2022)
	Details of fee submitted	PKR 75,000/-: dated: 04-07-2022 (Invoice # 461158715405)
	The proposed proprietary name / brand name	Omzole Delayed Release Capsule 40 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed released capsule contains: Omeprazole enteric coated pellets equivalent to Omeprazole ..... 40 mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule containing enteric coated pellets.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 30's, 50's, 60's, 100's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Losec®.

	For generic drugs (me-too status)	Risek 40 mg by Getz
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board approval in 282nd meeting for amendment in Tablet (General) Section.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 12-06-2025 **Giver:** GMP certificate valid up to: 01-02-2025
	Name and address of API manufacturer.	**Omeprazole E.C Pellets 10%** **Name:** Metrochem API Private Limited **Address:** Plot # D-69, Phase I, IDA Jeedimetla, Hyderabad, India. **GMP Validity:** 07-07-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Capsule Risek 40mg **Manufacturer:** M/s Getz **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Omeprazole E.C Pellets 10%** **Name:** Metrochem API Private Limited **Address:** Plot # D-69, Phase I, IDA Jeedimetla, Hyderabad, India.
API Lot No.	OMP/P/2/2021040658
Description of Pack (Container closure system)	Capsule 40mg packed in ALU-ALU blister, further packed in unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	021C081	022C081	023C081
Batch Size	300000 Capsules	300,000 Capsules	300000 Capsules
Manufacturing Date	11-2019	02-2020	06-2020
Date of Initiation	06-12-2019	06-03-2020	06-07-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 150 kg **Invoice #** BE/18/157 **Dated:** 07-02-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit evidence for GMP compliance status of Daneen Pharma. • Please submit GMP certificate of Genix Pharma which should be valid till date **OR** submit inspection report of the firm conducted within last three (03) years for confirmation of GMP compliance status of manufacturing facility for Capsule (General) Section. • Letter issued by Licensing Division DRAP for Approval of manufacturing facility of Tablet (General) Section by Central Licensing Board. • Please submit Contract agreement between two parties for the manufacturing of **Omzole Capsule 40 mg.**	All documents have been submitted by firm.
1.6.5	• Please submit GMP Certificate of API suppliers for Vonoprazan and Aspirin which should be in force till date.	Submitted
3.2.P.8	• Please submit clearance document from DRAP for procurement of API.	Submitted

Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
190.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma (Pvt) Ltd. (DML # 000688) 27-Sundar Industrial Estate Sundar Raiwind Road Lahore.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Genix Pharma (Pvt) Ltd. (DML # 000351) 44-45/B Korangi Creek Raod Karachi**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26858 (dated: 22-09-2022)
	Details of fee submitted	PKR 75,000/-: dated: 05-08-2022 (Invoice # 8757848671)
	The proposed proprietary name / brand name	DapazinM 5/850 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin .....5 mg Metformin HCl 850mg
	Pharmaceutical form of applied drug	Oral film coated tablet
	Pharmaco-therapeutic Group of (API)	Oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 28s & 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Xigduo 5/850®. By AstraZeneca (PLGB 17901/0343)
	For generic drugs (me-too status)	Daplyza-M 5/850 tablet by Getz
	Section Approval Letter from Licensing Division of DRAP	Approval letter for **Tablet (General) Section** in 282nd meeting of Central Licensing Board.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 14-06-2023 **Giver:** GMP certificate valid up to: 01-02-2025
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate** **Name:** Jiangsu Yongan Pharmaceutical. Co. Ltd. **Address:** No. 18, 237 provincial Road, Economic Development Zone, Huaian Jiangsu, China. **GMP Validity:** 31-12-2027 **Metformin HCl**

		Name: Shouguang Fukang Pharmaceutical Co. Ltd. **Address:** North East of Dongwaihuan Road, Dongcheng Industrial Area, China. **GMP Validity:** 03-07-2025
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	**Dapagliflozin propanediol monohydrate** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months **Metformin HCl** Stability study conditions: **Real time:** 30˚C ± 2˚C / 75% ± 5% RH for 24 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** DAPA-MET 5/850 Tablet **Manufacturer:** M/s Hilton **Testing parameters:** Innovator Specifications **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.
STABILITY STUDY DATA		
Manufacturer of API		**Dapagliflozin propanediol monohydrate** **Name:** Jiangsu Yongan Pharmaceutical. Co. Ltd. **Address:** No. 18, 237 provincial Road, Economic Development Zone, Huaian Jiangsu, China. **Metformin HCl**

	Name: Shouguang Fukang Pharmaceutical Co. Ltd. **Address:** North East of Dongwaihuan Road, Dongcheng Industrial Area, China.		
API Lot No.	**Dapagliflozin**	**Metformin HCl**	
	7100-202006001	P510-2004010	
Description of Pack (Container closure system)	Capsule 40mg packed in ALU-ALU blister, further packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	001T333	002T333	003T333
Batch Size	100,000 Tablets	100,000 Tablets	100,000 Tablets
Manufacturing Date	22-03-2021	22-03-2021	24-03-2021
Date of Initiation	11-05-2021	11-05-2021	11-05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Metformin HCl **Quantity:** 1000kg **Invoice #** SDKY20200908 **Dated:** 01-10-2020 Dapagliflozin **Quantity:** 10kg **Invoice #** ZY2012010 **Dated:** 16-12-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit evidence for GMP compliance status of Daneen Pharma. • Please submit GMP certificate of Genix Pharma which should	Submitted

	be valid till date **OR** submit inspection report of the firm conducted within last three (03) years for confirmation of GMP compliance status of manufacturing facility for Capsule (General) Section. • Please submit Contract agreement between two parties for the manufacturing of **DapazinM 5/850 Tablet.**		
1.5.2	• Please clarify with reference that how dapagliflozin propanediol monohydrate is equivalent to Sitagliptin?	Typographical mistake has been corrected.	
1.6.5	• Please submit GMP Certificate of API suppliers for Dapagliflozin and Metformin HCl which should be in force till date.	Submitted	
3.2.P.8	• Please submit clearance documents from DRAP for procurement of API from both suppliers.	Submitted	

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

191.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma (Pvt) Ltd. (DML # 000688) 27-Sundar Industrial Estate Sundar Raiwind Road Lahore.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Genix Pharma (Pvt) Ltd. (DML # 000351) 44-45/B Korangi Creek Raod Karachi**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4536 (dated: 16-02-2022)
	Details of fee submitted	PKR 75,000/-: dated: 05-08-2022 (Invoice # 9777482442)
	The proposed proprietary name / brand name	Ferric-M Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10 ml dispersion contains: Ferric Carboxymaltose complex equivalent to Iron .....500 mg
	Pharmaceutical form of applied drug	IV solution for injection
	Pharmacotherapeutic Group of (API)	Iron trivalent preparation (Hematinic)
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ferinject injection by Vifor France MHRA UK approved PL 15240/0002
	For generic drugs (me-too status)	Fercari Injection by Hilton
	Section Approval Letter from Licensing Division of DRAP	Approval letter for **Liquid Injectable (Vials/ampoules/infusion)** in 229th meeting of Central Licensing Board.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to: 12-06-2025 **Giver:** GMP certificate valid up to: 01-02-2025
	Name and address of API manufacturer.	**Name:** Nanjing Hencer Pharmaceutical Co. Ltd. **Address:** No. 18, Jichang Road Lishui Economic & technological Development Zone, Jiangsu, China. **GMP Validity:** 01-01-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug Substance)	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5% RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** FCM injection **Manufacturer:** M/s Genix **Testing parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** Nanjing Hencer Pharmaceutical Co. Ltd. **Address:** No. 18, Jichang Road Lishui Economic & technological Development Zone, Jiangsu, China.
API Lot No.	R210702

Description of Pack (Container closure system)	500mg/10ml in 10ml clear glass vial clip with magenta color cap. Futher pack in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	0041360	0021360	0031360
Batch Size	1980 vials	1980 vials	1980 vials
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	07-09-2021	23-08-2021	03-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 20kg **Invoice #** 21BT031 **Dated:** 30-06-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit evidence for GMP compliance status of Daneen Pharma. • Please submit GMP certificate of Genix Pharma which should be valid till date **OR** submit inspection report of the firm conducted within last three (03) years for confirmation of GMP compliance status of manufacturing facility for Capsule (General) Section. • Please submit Section Approval letter issued by Central Licensing Board for Sterile Liquid Ampoule (General) Section of Genix Pharma. • Please submit Contract agreement between two parties for the manufacturing of **Ferric-M Injection.**	Submitted
3.2.P.8	• Please submit clearance documents from DRAP for procurement of API LOT # R210702.	Submitted

Decision: Approved with Innovator Specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
192.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Well & Well Pharma (Pvt) Ltd. (DML # 000687) Plot No.7 Street S-8 National Industrial Zone RCCI Rawat.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Global Pharmaceuticals Pvt. Ltd (DML # 000417) Plot No. 204-205 Industrial Triangle Kahuta Road Islamabad.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6120 (dated: 03-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 18-11-2022 (Invoice # 969401152800)
	The proposed proprietary name / brand name	NEODROP-D 5mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of injection contains: cholecalciferol (Vitamin D3)..... 5 mg (200,000 IU)
	Pharmaceutical form of applied drug	Sterile solution for IM injection
	Pharmacotherapeutic Group of (API)	Vitamin D_3
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1s, 1 x 5s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ASNM France approved (CIS: 6 659 708 3)
	For generic drugs (me-too status)	ED3 Injection by GT Pharma
	Section Approval Letter from Licensing Division of DRAP	Injectable vials/ampoules approved in 155th meeting of Central Licensing Board.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 02-01-2024 **Giver:** GMP certificate valid up to 07-12-2023
	Name and address of API manufacturer.	**Name:** M/s Sichuan Province Yuxin Pharmaceutical Co. Ltd. **Address:** Weicheng Jinhe Est Road, Shifang City, Sichuan Province, China. China. **GMP Validity:** 02-02-2024

	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Miura-D injection **Manufacturer:** M/s Getz **Testing parameters:** Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Sichuan Province Yuxin Pharmaceutical Co. Ltd. **Address:** Weicheng Jinhe Est Road, Shifang City, Sichuan Province, China.		
API Lot No.	VD3201115 (2101R0074)		
Description of Pack (Container closure system)	Colorless clear oily solution filled in clear glass ampoules with red spot and imprinted with calciferol and other specs in orange color		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21F001	21L010	
Batch Size	60,870 Ampoules	60,870 Ampoules	
Manufacturing Date	06-2021	11-2021	
Date of Initiation	29-06-2021	13-12-2021	
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 15kg **Clearance date:** 05-01-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	• Please submit GMP certificate of API supplier issued by regulatory authority of country of origin and should be in force till date.	Submitted

Decision: Approved with Innovator Specifications.

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

193.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Vision Pharmaceuticals (DML # 000517) Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Global Pharmaceuticals Pvt. Ltd (DML # 000417) Plot No. 204-205 Industrial Triangle Kahuta Road Islamabad.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4382 (dated: 15-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 03-02-2023 (Invoice # 8900236074)

	The proposed proprietary name / brand name	Opepzole 40 mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard Gelatin capsule contains: Omeprazole enteric coated pellets equivalent to Omeprazole ..... 40 mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule containing enteric coated pellets
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10s, 14s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Risek Capsule 40 mg **Manufacturer:** M/s Getz
	Section Approval Letter from Licensing Division of DRAP	Inspection report submitted conducted for renewal of DML of the firm mentioning the Capsule (General) Section.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 02-01-2024 **Giver:** GMP certificate valid up to 12-01-2025
	Name and address of API manufacturer.	**8.5% Enteric coated pellets of Omeprazole** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad. **GMP Validity:** 13-06-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Capsule Risek 40 mg **Manufacturer:** M/s Getz **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**<u>8.5% Enteric coated pellets of Omeprazole</u>** **Name:** M/s Vision Pharmaceuticals (Pvt.) Ltd. **Address:** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	OMP1172		
Description of Pack (Container closure system)	Off white to pale yellow spherical pellets filled in empty hard gelatin capsules.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	22C098	22C102	
Batch Size	200,000 Capsules	200,000 Capsules	
Manufacturing Date	03-2022	03-2022	
Date of Initiation	03-04-2022	04-04-2022	
No. of Batches	03		

Administrative Portion

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

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit Section approval letter issued by Central Licensing Board for Capsule (General) Section of Global Pharmaceuticals	Submitted

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

194.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma (Pvt) Ltd. (DML # 000045)** **Plot No.10 & 25 Sector 20 Korangi Industrial Area Karachi.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s NovaMed Pharmaceuticals (Pvt) Ltd.** **28-Km Ferozepur Road Lahore. (DML # 000590)**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5905 (dated: 02-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 10-01-2023 (Invoice # 7736599368)
	The proposed proprietary name / brand name	Aspimox infusion 400 mg / 250 ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml contains: Moxifloxacin (as HCl)..... 400 mg
	Pharmaceutical form of applied drug	Sterile solution of infusion
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	In-house Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Moxiget 400mg/250 ml **Manufacturer:** M/s Getz
	Section Approval Letter from Licensing Division of DRAP	Renewal of DML letter dated 14th September 2021 Liquid Injectable ampoule / vial General – Revised Approved in 282nd meeting of Central Licensing Board 31-08-2023.

	GMP status of the Finished product manufacturer	**Acceptor:** Good-inspection report dated 06-08-2021
	Name and address of API manufacturer.	**Name:** M/s AARTI Drugs Limited. **Address**: Plot # G-60, MIDC Tarapur, TAL: PALGHAR DIST. THANE, MIDC TARAPUR-BOISAR Taluka: Palghar, District: Thane-Zone 04 India. **GMP validity :** 31-12-2026.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 12 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Avelox infusion **Manufacturer:** M/s Bayer **Testing parameters:** in-house Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA	
Manufacturer of API	**Name:** M/s AARTI Drugs Limited. **Address**: Plot # G-60, MIDC Tarapur, TAL:PALGHAR DIST. THANE, MIDC TARAPUR-BOISAR Taluka: Palghar, District: Thane-Zone 04 India.
API Lot No.	MOXI/2103009
Description of Pack (Container closure system)	Glass vial 250ml
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	15675	15874	15871
Batch Size	4000 packs	4000 packs	4000 packs
Manufacturing Date	07-2021	09-2021	07-2021
Date of Initiation	30-07-2021	24-09-2021	24-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 125 kg **Clearance date:** 04-02-2021 **Invoice#** EXP/2512/20-21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit fresh / valid GMP certificate of Aspin Pharma.	Submitted
3.2.S.7	• Please submit stability data of long term storage condition of API as per stability protocol. The minimum stability data should be for 24 months.	Submitted

Decision: Approved with Innovator Specifications.

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

195.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. (DML # 000267) Plot No. 37, Sector 19, Korangi Industrial Area Karachi.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt.) Ltd. 19-km, Sheikhupura Road, Faisalabad. (DML # 000616)**
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4214 (dated: 14-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 10-01-2023 (Invoice # 0583698163)
	The proposed proprietary name / brand name	Flutinase Nasal Spray
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each actuation delivers: 100 mg suspension containing Fluticasone Propionate .....50 mcg
	Pharmaceutical form of applied drug	Nasal spray
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	1's (60 metered sprays)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	**Brand Name:** Ticovate *(Reg. # 060353)* **Manufacturer:** M/s Saffron
	Section Approval Letter from Licensing Division of DRAP	Not provided
	GMP status of the Finished product manufacturer	**Acceptor:** GMP Certificate validity 02-01-2024. **Giver:** GMP Certificate validity 08-09-2024.
	Name and address of API manufacturer.	**Name:** M/s Aurisco Pharmaceutical Co. Ltd. **Address**: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China. **GMP validity :** 06-09-2025.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 75% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Flixonase Nasal Spray **Manufacturer:** M/s GSK **Testing parameters:** BP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Aurisco Pharmaceutical Co. Ltd. **Address**: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China.		
API Lot No.	AF-B200701, AF-B-210503		
Description of Pack (Container closure system)	Spray will be filled in amber colored spray bottle with actuator, packed din card board carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	B # 052	B # 053	B # 054
Batch Size	200 kg	200 kg	200 kg
Manufacturing Date	11-2021	01-2022	12-2021
Date of Initiation	19-11-2021	26-02-2022	15-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** 18885/2020-DRAP **Dated:** 24-12-2020 **Quantity:** 1.5 kg **Invoice #** 14797/2021-DRAP **Dated:** 05-10-2021 **Quantity:** 1.5 kg

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

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• Please submit Section approval letter for **Topical Spray (Steroid) Section** of Saffron Pharma approved in meeting of Central Licensing Board.	Firm has submitted inspection report of renewal of DML in which Nasal Spray section is mentioned with Cream/Ointment/Lotion/Nasal Spray (Steroidal) Section. Firm has now applied for regularization / grant of additional Section in Licensing Division.

Decision:
Deferred for confirmation of required manufacturing facility / section approval from Licensing Division.

196.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Sapient Pharma (DML # 000207) 123/S,104/s,Industrial Area, Kot Lakhpat, Lahore.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Bio-Mark Pharmaceuticals (DML # 000863) Plot No. 527, Sunder Industrial Estate, Lahore.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2984 (dated: 01-02-2023)
	Details of fee submitted	PKR 75,000/-: dated: 10-01-2023 (Invoice # 70855346983)
	The proposed proprietary name / brand name	Biowell Capsule 3/25
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard Gelatin capsule contains: Olanzapine..... 3mg Fluoxetine (as HCl) .....25 mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules
	Pharmacotherapeutic Group of (API)	Atypical antipsychotic & SSRI
	Reference to Finished product specifications	USP Specification

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation **Symbax®**
	For generic drugs (me-too status)	**Brand Name:** Co-Depricap capsule **Manufacturer:** M/s NabiQasim
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board in its 253rd meeting held on 15th & 16th May 2017 approved the grant of DML including Capsule (General) Section.
	GMP status of the Finished product manufacturer	Inspection report conducted on 13-02-2020.
	Name and address of API manufacturer.	**Fluoxetine (as HCl)** **Name:** M/s Palam Pharma Pvt. Ltd. **Address**: 12/C, Phase-I, Near Old Nirma, G.I.D.C. Estate, Vatva, Ahmedabad, Gujrat, India. **GMP validity:** 03-11-2025 **Olanzapine** **Name:** M/s Smilax Laboratories Limited **Address**: 12/A, Phase III, I.D.A Jeedimelta, Hyderabad, India. **GMP validity:** 30-09-2023
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Olanzapine** Stability study conditions: **Real time:** 30˚C ± 2˚C / 55% ± 5%RH for 48 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months **Fluoxetine (as HCl)** Stability study conditions: **Real time:** 30˚C ± 2˚C / 55% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Co-Depricap 3/25 tablet **Manufacturer:** M/s NabiQasim **Testing parameters:** USP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Fluoxetine (as HCl)** **Name:** M/s Palam Pharma Pvt. Ltd. **Address**: 12/C, Phase-I, Near Old Nirma, G.I.D.C. Estate, Vatva, Ahmedabad, Gujrat, India. **Olanzapine** **Name:** M/s Smilax Laboratories Limited **Address**: 12/A, Phase III, I.D.A Jeedimelta, Hyderabad, India.		
API Lot No.	**Olanzapine**	**Fluoxetine (as HCl)**	
	OLP H 1806009	FX/1808003	
Description of Pack (Container closure system)	**Primary container:** Capsules blister in Aluminum / Aluminum packing as 7s in two blisters (2 x 7s). **Outer container:** Two blisters will pack in cardboard printed carton along with leaf insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	20M566	20M565	20M566
Batch Size	100,000 Capsules	100,000 Capsules	100,000 Capsules
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Olanzapine** **Clearance date:** 19-10-2018 **Quantity:** 5 kg **Fluoxetine (as HCl)** **Invoice #** EXQST06 **Dated:** 30-06-2018 **Quantity:** 25kg

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

Remarks of the Evaluator:

Section	Observations	Status
1.3.4	• For Bio-Mark Pharmaceuticals, please submit GMP Certificate issued by DRAP and should be in force till date **OR** submit inspection report conducted within last three years to confirm the GMP compliance status of the manufacturing facility for **Capsule (General) Section.** • Please submit Section approval letter for **Capsule (General) Section** of Bio-mark Pharmaceuticals approved in meeting of Central Licensing Board. • Please submit contract agreement between two parties mentioning the names of drug products in it which are intended to be manufactured on contract basis. • Please submit GMP certificate of Sapient Pharma to confirm its GMP compliance status.	Submitted
1.6.5	• Please submit GMP certificate of API suppliers for both Olanzapine and Fluoxetine (as HCl) issued by regulatory authority of country of origin and should be in force till date.	Submitted
3.2.P.8	• Please submit DRAP clearance documents for procurement of fluoxetine HCl manufactured by Palam Pharma Pvt. Ltd. Gujarat, India.	Submitted

Decision: Approved.

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

197.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd. (DML # 000284) Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt.) Ltd. 19-km, Sheikhupura Road, Faisalabad. (DML # 000616)**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6361 (dated: 06-03-2023)

	Details of fee submitted	PKR 75,000/-: dated: 07-02-2023 (Invoice # 7466481766)
	The proposed proprietary name / brand name	Azeflu Plus Nasal Spray 137mcg + 50 mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Spray / actuation (0.14gm) contains: Azelastine .....137 mcg Fluticasone Propionate .....50 mcg
	Pharmaceutical form of applied drug	Nasal spray in amber glass plastic bottle containing 120 metered sprays (23gm per bottle filling)
	Pharmacotherapeutic Group of (API)	Corticosteroid / anti-allergic
	Reference to Finished product specifications	In-House Specification
	Proposed Pack size	25ml Amber glass plastic bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved **Dymista®**
	For generic drugs (me-too status)	N/A
	Section Approval Letter from Licensing Division of DRAP	Not provided
	GMP status of the Finished product manufacturer	**Acceptor:** GMP Certificate validity 02-01-2024. **Giver:** GMP Certificate validity 13-01-2024.
	Name and address of API manufacturer.	**Fluticasone Propionate** **Name:** M/s Aurisco Pharmaceutical Co. Ltd. **Address**: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China. **GMP validity:** 06-09-2025. **Azelastine** **Name:** M/s Curia Italy SRL **Address**: Via Volturno, 41/43 (entrata principale)-Via Volturno, 45/48 (Entrata secondria)-20089 Rozzano (MI), Italy. **GMP validity :** expired.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Fluticasone propionate** Stability study conditions: **Real time:**

		30˚C ± 2˚C / 75% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months **Azelastine** Stability study conditions: **Real time:** 30˚C ± 2˚C / 75% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Dymista Nasal Spray **Manufacturer:** M/s Meda Pharmaceuticals Germany **Testing parameters:** In-House Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Fluticasone Propionate** **Name:** M/s Aurisco Pharmaceutical Co. Ltd. **Address**: Badu Industrial Park Zone, Tiantai, Zheijiang Province, China. **GMP validity:** 06-09-2025. **Azelastine** **Name:** M/s Curia Italy SRL **Address**: Via Volturno, 41/43 (entrata principale)- Via Volturno, 45/48 (Entrata secondria)-20089 Rozzano (MI), Italy. **GMP validity :** expired.		
API Lot No.			
Description of Pack (Container closure system)	Amber colored Pastic spray bottle with white plastic spray (0.14g) / actuator, a blue clip lock and a transparent lid.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T – 003	T – 004	T – 005
Batch Size	200 kg	200 kg	200 kg
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	18-03-2022	18-03-2022	18-03-2022
No. of Batches	03		

Administrative Portion

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

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

Remarks of the Evaluator:

Section	Observations
1.3.4	• Please submit Section approval letter for **Topical Spray (Steroid) Section** of Saffron Pharma approved in meeting of Central Licensing Board.
1.6.5	• Please submit GMP certificate of API manufacturer of Azelastine HCl issued by regulatory authority of country of origin and should be inforce till date.
3.2.P.7	• Please mention the exact pack size / presentation and number of actuation per container both in ml and grams. • Please submit data and documentation to support the initial priming (6 actuations) and repriming (at least one actuation) as stated in the labels and Product Information (PI).
3.2.P.8	• Has firm performed investigation on the particle size distribution of the suspended particles for both actives in the formulation of the drug product? • Please justify that why Delivered Dose Uniformity, Particle Size Distribution and Droplet Size Distribution for effective dose delivery to the nasal cavity have not been included in the finished product specifications while it is part of the innovator's specifications? • Please submit supportive data regarding in use stability of opened product. • Please submit DRAP clearance documents for procurement of both APIs.

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

198.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited.** **(DML # 000141)** **Plot No. F-216, S.I.T.E. Karachi.**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s Vision Pharmaceuticals (Pvt.) Ltd.** **Plot # 22-23 Industrial Triangle, Kahuta Road, Islamabad. (DML # 000517)**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34959 (dated: 02-12-2022)
	Details of fee submitted	PKR 75,000/-: dated: 22-11-2022 (Invoice # 239485016)
	The proposed proprietary name / brand name	Sante Insta 20mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Omeprazole ..... 20 mg Sodium Bicarbonate .....1680 mg
	Pharmaceutical form of applied drug	Oral powder for reconstitution packed in Sachet
	Pharmacotherapeutic Group of (API)	A combination of PPI & antacid
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved **Zegerid®**
	For generic drugs (me-too status)	Risek Insta 20 mg Sachet by Getz
	Section Approval Letter from Licensing Division of DRAP	Letter of Renewal of DML dated 07-06-2021 **Sachet (General) Section** Renewal approved in 278th meeting of Central Licensing Board dated 10th & 11th December 2020.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 12-01-2025
	Name and address of API manufacturer.	**<u>Omeprazole: sodium carbonate</u>** ***MANUFACTURING FACILITY (UNIT I – API)*** **Name:** Metrochem API Private Limited **Address:** Plot No.62/C/6. Pipe Line Road, Phase 1, IDA, Jeedimetla, Hyderabad, Rangareddy, Telangana State 500055, India. **GMP Validity:** 07-05-2027
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**<u>Omeprazole</u>** Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Risek insta Sachet 20 mg **Manufacturer:** M/s Getz **Testing parameters:** In-House Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**<u>Omeprazole: Sodium Bicarbonate</u>** ***MANUFACTURING FACILITY (UNIT I – API)*** **Name:** Metrochem API Private Limited **Address:** Plot No.62/C/6. Pipe Line Road, Phase 1, IDA, Jeedimetla, Hyderabad, Rangareddy, Telangana State 500055, India. **GMP Validity:** 07-05-2027		
API Lot No.	**Sodium Bicarbonate**	**Omeprazole**	
	2020050911	2106R0079	
Description of Pack (Container closure system)	Packed in Sachet made of aluminium foil.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21M023	21M024	21M037
Batch Size	2000 sachets	2000 sachets	2000 sachets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	20-12-2021	20-12-2021	22-12-2021
No. of Batches	03		

Administrative Portion

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**<u>Omeprazole: Sodium Bicarbonate</u>** **Invoice #** AE/21-22/0087 **Clearance date:** 16-06-2021 **Quantity:** 500kg **Invoice #** 2101-000008 **Dated:** 04-01-2021 **Quantity:** 300kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	• Please submit GMP certificate of both API manufacturer of sodium bicarbonate issued by regulatory authority of country of origin and should be inforce till date.	Submitted
1.3.4	• Please submit GMP certificate of Contract giver Macter International Limited.	Submitted
3.2.P.3.2	• Please justify that why Caster sugar has been chosen instead of Xylitol.	Submitted

Decision: Approved with Innovator Specifications.

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

199.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. (DML # 000141) Plot No. F-216, S.I.T.E. Karachi.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle, Kahuta Road, Islamabad. (DML # 000517)**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 34960 (dated: 02-12-2022)
	Details of fee submitted	PKR 75,000/-: dated: 29-11-2022 (Invoice # 940117139936)
	The proposed proprietary name / brand name	Sante Insta 40mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Omeprazole ..... 40 mg Sodium Bicarbonate .....1680 mg
	Pharmaceutical form of applied drug	Oral powder for reconstitution packed in Sachet
	Pharmacotherapeutic Group of (API)	A combination of PPI & antacid
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved **Zegerid®**
	For generic drugs (me-too status)	Risek Insta 40 mg Sachet by Getz
	Section Approval Letter from Licensing Division of DRAP	Letter of Renewal of DML dated 07-06-2021 **Sachet (General) Section** Renewal approved in 278th meeting of Central Licensing Board dated 10th & 11th December 2020.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 12-01-2025
	Name and address of API manufacturer.	**Omeprazole: Sodium Bicarbonate** ***MANUFACTURING FACILITY (UNIT I – API)*** **Name:** Metrochem API Private Limited **Address:** Plot No.62/C/6. Pipe Line Road, Phase 1, IDA, Jeedimetla, Hyderabad, Rangareddy, Telangana State 500055, India. **GMP Validity:** 07-05-2027
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Omeprazole: Sodium Bicarbonate** Stability study conditions: **Real time:** 30°C ± 2°C / 65% ± 5%RH for 60 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Stability study conditions:
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Risek insta Sachet 40 mg **Manufacturer:** M/s Getz **Testing parameters:** In-House Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**<u>Omeprazole : Sodium Bicarbonate</u>** ***MANUFACTURING FACILITY (UNIT I – API)*** **Name:** Metrochem API Private Limited **Address:** Plot No.62/C/6. Pipe Line Road, Phase 1, IDA, Jeedimetla, Hyderabad, Rangareddy, Telangana State 500055, India. **GMP Validity:** 07-05-2027		
API Lot No.	**Sodium Bicarbonate**	**Omeprazole**	
	2020050911	2106R0079	
Description of Pack (Container closure system)	Packed in Sachet made of aluminium foil.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21L068	21L069	21L041
Batch Size	2000 sachets	2000 sachets	2000 sachets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	27-11-2021	27-11-2021	27-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** AE/21-22/0087 **Clearance date:** 16-06-2021 **Quantity:** 500kg

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

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	• Please submit GMP certificate of API manufacturer of sodium bicarbonate issued by regulatory authority of country of origin and should be inforce till date.	Submitted
1.3.4	• Please submit GMP certificate of Contract giver Macter International Limited.	Submitted
3.2.P.3.2	• Please justify that why Caster sugar has been chosen instead of Xylitol.	Submitted

Decision: Approved with Innovator Specifications.

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

200.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries (Pvt) Ltd. (DML # 000105) 17/24 Korangi Industrial Area Karachi.**
	Contract Acceptor Name, address of Manufacturing site.	**M/s Surge Laboratories (Pvt) Ltd. (DML # 000484) 10-Km Faisalabad Road Bhikhi Distt: Sheikhupura.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33967 (dated: 24-11-2022)
	Details of fee submitted	PKR 75,000/-: dated: 04-11-2022 (Invoice # 6111307786)
	The proposed proprietary name / brand name	Reliefal IV infusion 1000mg/100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Paracetamol BP .....1000 mg
	Pharmaceutical form of applied drug	Sterile Solution for infusion

	Pharmacotherapeutic Group of (API)	Antipyretic/analgesic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	100 ml glass vial as a sterile liquid ready to use solution for intravenous infusion in a single pack.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	HPRA Ireland approved formulation.
	For generic drugs (me-too status)	Bofalgan infusion by Bosch.
	Section Approval Letter from Licensing Division of DRAP	Letter of Renewal of DML dated 11-01-2022 **Liquid injectable (including blow fill seal area)** Renewal approved in 284th meeting of Central Licensing Board dated 16th December 2022.
	GMP status of the Finished product manufacturer	**Acceptor:** GMP certificate valid up to 04-10-2023
	Name and address of API manufacturer.	**Name:** M/s Citi Pharma (Pvt.) Ltd. (DML # 000429) **Address:** 3-km, Head Balloki Road, Bhai pheru, District Kasur. **GMP Validity:** 16-12-2026
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Bofalgan IV Infusion. **Manufacturer:** M/s Bosch **Testing parameters:** In-House Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system

		suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s Citi Pharma (Pvt.) Ltd. (DML # 000429) **Address:** 3-km, Head Balloki Road, Bhai pheru, District Kasur.		
API Lot No.	PGP21-481		
Description of Pack (Container closure system)	100ml clear molded glass vial USP type II		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	PIV-100-039	PIV-100-040	PIV-100-041
Batch Size	20 Vials	20 Vials	20 Vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-2022	03-2022	03-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** CP21-9340 **Clearance date:** 30-11-2021 **Quantity:** 1000kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations	Status
1.6.5	• Please submit GMP certificate of API manufacturer which should be inforce till date.	Submitted
1.3.4	• Please submit GMP certificate of Contract giver NabiQasim Industries which should be inforce till date. • Please submit GMP certificate of Contract Acceptor Surge Laboratories which should be inforce till date.	Submitted

Decision: Approved with Innovator Specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
201.	**Contract Giver** **Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Health Care (Pvt) Ltd** **(DML # 000856)** **Plot No. 35-A, Small Industrial Estate, Taxila**
	Contract Acceptor **Name, address of Manufacturing site.**	**M/s Wenovo Pharmaceuticals (DML # 000790)** **Plot No. 31 & 32 Punjab Small Industrial Estate, Taxila Rawalpindi.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35341 (dated: 06-12-2022)
	Details of fee submitted	PKR 75,000/-: dated: 16-11-2022 (Invoice # 12857546)
	The proposed proprietary name / brand name	Iboxime Capsule 200 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard Gelatin capsule contains: Cefixime (as Tri-hydrate) ..... 200 mg
	Pharmaceutical form of applied drug	Hard gelation capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	JP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIMA Spain approved
	For generic drugs (me-too status)	Soxime by Swat Pharma
	Section Approval Letter from Licensing Division of DRAP	Central Licensing Board in its 233rd meeting held on 30th & 31st December 2013 approved the grant of Drug Manufacturing License, DML # 000790 including manufacturing facility for **Capsule (Cephalosporin) Section.**
	GMP status of the Finished product manufacturer	**Acceptor:** not provided **Giver:** not provided
	Name and address of API manufacturer.	**Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore. **GMP Validity**: 17-11-2024

	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 36 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Name:** Cifam Capsule 200mg. **Manufacturer:** M/s Hilton **Testing parameters:** JP Specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Pharmagen Limited. **Address:** Kot Nabi Baksh Wala, 34-km Ferozpur Road, Lahore.		
API Lot No.	00244/067/2020		
Description of Pack (Container closure system)	ALU-ALU blisters of 1 x 5's further packed in Bleach card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	C-379	C-403	C-409
Batch Size	15000 Packs	15000 Packs	15000 Packs
Manufacturing Date	05-2020	07-2020	08-2020
Date of Initiation	20-05-2020	25-07-2020	06-08-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Invoice #** CP21-9340 **Clearance date:** 30-11-2021 **Quantity:** 1000kg
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Section	Observations
1.3.4	• Please submit GMP certificate of Contract Giver Horizon HealthCare issued by DRAP which should be inforce till date **OR** inspection report conducted within last 03 years • Please submit GMP certificate of Contract Acceptor Wonovo Pharmaceuticals issued by DRAP which should be inforce till date **OR** inspection report conducted within last 03 years.
3.2.P.8	• Please submit stability data sheets for accelerated and long term stability conditions for the results of analytical tests performed as per JP specifications along with raw data, calculation sheets and chromatograms.

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

Item No. 05: Deferred Cases:

202.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals. (DML # 000885) 7-km, Pasrur Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals. (DML # 000885) 7-km, Pasrur Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 08th February 2023 Purpose of inspection: grant of GMP certificate. Manufacturer's overall rating: A (Good)
	Evidence of approval of manufacturing facility	Central Licensing Board in its 265th meeting held on 09th & 10th August 2018 approved the grant of DML #

		000885 (Formulation) including Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 19140 dated 30-06-2022
	Details of fee submitted	PKR 30,000/- Dated: 13-01-2022 Slip # 51388217
	The proposed proprietary name / brand name	Tablet Metrozole 400 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Metronidazole .....400 mg
	Pharmacotherapeutic Group of (API)	Nitroimidazole antimicrobials.
	Pharmaceutical form of applied drug	Film coated tablets
	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	Flagyl® USFDA approved formulation
	For generic drugs (me-too status)	Flagyl by M/s Sanofi (Reg. # 000827)
	Name and address of API manufacturer.	Name: M/s AARTI Drugs Limited. Address: Mahendra Industrial Estate, Plot # 109-D, Road No. 29, Sion (East) Mumbai, India. **GMP validity :** 17-02-2025
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties,solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 24 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Reference product:** Tablet Flagyl 400 mg **Manufactured by:** Sanofi **Testing parameters:** USP Specifications. **Comparative Dissolution Profile** Firm has submitted comparative dissolution profile in three mediums showing similarity between the manufacturer's product and the reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s AARTI Drugs Limited. Address: Mahendra Industrial Estate, Plot # 109-D, Road No. 29, Sion (East) Mumbai, India.		
API Lot No.	MTZ/0050700		
Description of Pack (Container closure system)	Yellow color, biconvex, unscored film coated tablets, in ALU-ALU Blister packed in cardboard unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 6 (Months) Real Time: 0, 6 (Months)		
Batch No.	21TRn010	21TRn011	20TRn023
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	08-2021	08-2021	12-2020
Date of Initiation	09/2021	09/2021	09/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last Product Specific Inspection of the firm was conducted for Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet, for which the inspection was conducted on 14-03-2019 and the report was presented in 289th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR compliant. Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of	**Quantity:** 5 KG **Dated:** 04-11-2020

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

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.3.4	Please submit inspection report of manufacturing unit conducted within last 03 years and a readable photocopy for issuance/grant of sections for manufacturing of dosage form(s) by Central Licensing Board.	Submitted
3.2.P.8	Please submit stability data of the interval **"06th month"** for both accelerated and real time storage conditions.	Submitted
	Please submit GMP certificate of API supplier which should be in force till date.	Submitted
	Please submit COA of API used in product development and manufacturing of stability batches.	Submitted
	Please submit DRAP Clearance document for procurement of API.	Submitted

Decision: Approved.

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

203.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt.) Ltd. (DML # 000805) 36-km, Lahore – Gujranwala Road, Khori Dstrict Sheuikhupura.**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt.) Ltd. (DML # 000805) 36-km, Lahore – Gujranwala Road, Khori Dstrict Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid till 13-02-2025
	Evidence of approval of manufacturing facility	Section granted by CLB in 282nd meeting
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22881 dated 12-08-2022

	Details of fee submitted	PKR 30,000/-: Dated 19-07-2022 Slip # 871109892
	The proposed proprietary name / brand name	Sodium Valproate 5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Sodium Valproate equivalent to Valproic acid… 500mg/5ml
	Pharmacotherapeutic Group of (API)	Anti- Epileptics / Anti-Convulsants
	Pharmaceutical form of applied drug	Clear Colourless Solution for Injection packed in clear glass ampoule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	5mlx1's, 5mlx5's, 5mlx10's,
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEPACON® Manufactured by: Hospira, Inc.. for AbbVie Inc. Approved by: USFDA
	For generic drugs (me-too status)	Epival by Abbot Laboratories Reg# 076295
	Name and address of API manufacturer.	Name: Sun Pharmaceutical Industries Ltd Address: Sathammai Village, Karunkhazi Post Madhuranthagam Taluk Kancheepuram District Tamil Nadu 603 303, India GMP Validity: *not provided*
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Epival Manufactured by: Abbot Laboratories Testing Parameters: Innovator Specifications
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: Sun Pharmaceutical Industries Ltd Address: Sathammai Village, Karunkhazi Post Madhuranthagam Taluk Kancheepuram District Tamil Nadu 603 303, India		
API Lot No.	SDMNF20339		
Description of Pack (Container closure system)	Clear glass ampoule, with red printing arrange in PVC tray and packe din Bleach card unit box with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	SV-0121	SV-0221	SV-0321
Batch Size	200 Ampoules	200 Ampoules	200 Ampoules
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	22-02-2021	23-02-2021	23-02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 0.050kg **Dated:** 19-01-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section	Observations	Reply of the firm
1.6.5	Please submit valid GMP Certificate of API supplier issued by regulatory authority of country of origin and should be in force till date.	Submitted along with prescribed fee of PKR 30,000/- *(Slip #)*
3.2.P.2	Innovator specifications are not acceptable after publication of monograph in official Pharmacopeia. Please submit Pharmaceutical equivalence studies as per testing procedure provided in monograph of official Pharmacopeia.	Submitted
3.2.P.8	Please submit DRAP clearance documents for procurement of API.	Submitted
	Innovator specifications are not acceptable after publication of monograph in official Pharmacopeia. Please submit stability data for the three batches for all the test mentioned in monograph of official pharmacopeia and perform assay of drug product on HPLC and submit data accordingly.	• Firm clarified that the results of analysis using HPLC & UV spectrophotometer are comparable with RSD = 0.329. • They also mentioned that all the results mentioned in previously submitted report with innovator specifications falls under the limits defined in USP specifications and accordingly submitted stability sheets of 03 batches with limits of testing parameters as per USP specifications. • They have submitted the batch analysis data of the above mentioned stability which has been recently tested now on HPLC and chromatograms have been submitted along with calculation sheets ensuring that product is stable even after 24 months. • Now they requested to considerthe approval of their formulation on the basis of the batch analysis report recently conducted on stability batches as per USP pharmacopeia and submitted undertaking that they will follow HPLC method of USP pharmacopeia for onward testing of their drug product for commercial batches.

Decision: Deferred for submission of stability study data of three batches of drug product as per the analytical testing method & specifications provided monograph of drug product in the latest edition of USP pharmacopeia.

204.	**Name of the medicinal product to be imported:**	**Diprofol EDTA 10mg / ml (1%)** Each 1ml of emulsion contains Propofol 10mg
	Name, address of Applicant / Importer	**Bristol Mayer Biotech Pakistan** **Head Office Address:** **73-B, Guldasht Town, Zarrar Shaheed Road, Lahore – Cantt.**

	Details of Drug Sale License of importer	License No: 05-352-0068-029407D Address: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore – Cantt. Validity: 07-04-2027. Status: License to sell drugs as a distributor Renewal: N/A
	Name and address of marketing authorization holder (abroad)	Joint Stock Company "FARMAK" Address: 63, Kyrylivska Street, Kyiv, 04080 Ukraine.
	Name, address of manufacturer(s)	Name: Joint Stock Company "FARMAK" Address: 74, Kyrylivska St., Kyiv, 04080, Ukraine; 4, Chornomorska St., Kyiv, 04080, Ukraine.
	Name of exporting country	Ukraine
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP (Original & Legalized): Firm has submitted original, legalized CoPP Product License: UA/15942/01/01 Date of Issue: 16-11-2021 Date of Legalization: 31-07-2023 GMP validity: 13-12-2024 Issued by: State Service of Ukraine on Medicines & Drugs Control, 120-A Peremohy Avenue, Kyiv, Ukraine. 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.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from JSC FARMAK, a legal entity organized and existing under the laws of Ukraine registered with Commercial Register at the Registration No: 00481198 Tax Payer Registration No. in Ukraine: 3150525658 Date of Authorization: 04-07-2019 Details of entity authorized in Pakistan: Bristol Mayer Biotech Pakistan Head Office Address: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore – Cantt.
	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 ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 22828 Dated: 18-09-2023

	Details of fee submitted	PKR 150,000/-: 16-08-2023 Slip # 5742933198
	The proposed proprietary name / brand name	DIPROFOL EDTA 10mg/ml Emulsion for injection/infusion.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1 ml of emulsion contains: Propofol..... 10mg
	Pharmaceutical form of applied drug	Sterile emulsion of injection
	Pharmacotherapeutic Group of (API)	General Anesthesia
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack size	20 ml vial (1's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Diprivan® USFDA approved formulation.
	For generic drugs (me-too status)	B.Braun formulation
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: Bachem S.A. Address: Route Du Simplon 22, 1895 Vionnaz, Switzerland.
	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)	Recommended EDQM storage conditions for unopened container: 5 ^{o}C ±3^{o}C
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients,control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Name: Diprivan® Manufacturer: Aspen Pharma Trading Ltd Ireland.
	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 ampoule
	Stability study data of drugproduct, shelf life and storageconditions	*Firm has submitted stability data both of vials and ampoule dosage form (20ml ampoules, 20ml vials & 100 ml vials) both at accelerated as well as long term stability conditions.* Accelerated Stability conditions: (06 months) Temperature: 40 ± 2ºC Relative Humidity: 75 ± 5% Long term stability conditions (12 months) Temperature: 30 ± 2ºC Relative Humidity: 75 ± 5%

Evaluation by PEC:

Section	Observations	Status
1.5.4	Please mention a single dosage form along with single pack size i.e. **Ampoule OR vial.** Multiple dosage form and multiple pack size of Ampoule and vials cannot be allowed in a single registration letter.	20 ml vials has been selected with a single pack size.
3.2.S.7	Please submit stability data of minimum 03 commercial scale batches of API conducted by drug substance manufacturer at Zone IV-A storage conditions.	Certificate of suitability submitted for API issued by EDQM.
3.2.P.2	Please justify that how the Pharmaceutical equivalence studies of your drug product packed in vials and ampoule, a different primary container of drug product than prefilled syringes of **Diprivan 1% manufactured by Aspen Ireland.**	For pharmaceutical equivalence studies **Dprivan 1% & Diprivan2%** have been used as reference products. For our selected volume of 20ml vial, Disoprivan 1% 20ml vial Batch # RC20003C & Batch # RC 20007A Germany.
3.2.P.8	Please submit stability data of minimum 03 commercial scale batches of drug product with one dosage form **(vial OR ampoule)** with single pack size (20ml OR 50ml).	Firm has submitted only 12-month data for long term storage conditions for ZONE IV-A with explaination as under:

Explanation Letter

We, JSC «FARMAK» with legal address 63, Kyrylivska street, Kyiv, 04080, Ukraine would like to express our respect and to inform you about the stability studies of our product Diprofol EDTA 10 mg/mL or 20 mg/mL emulsion for injection/infusion.

We kindly confirm that the stability study of the drug product is performed in accordance with ICH Guideline Q1A (R2) Stability Testing of New Drug Substances and Products. Initial Long term stability studies were conducted under the conditions 30 ± 2 ºC / 75 ± 5% RH and at the time of the dossier submission to the Regulatory Authority of Pakistan, the product complied with all test parameters.

Later, it was discovered that in T18 the product does not meet the requirements according to the "Free fatty acids" indicator. Therefore, we provide information about 24 months of Diprofol

	EDTA 10 mg/mL or 20 mg/mL emulsion for injection/infusion stability studies under the conditions 25 ± 2°C / 60 ± 5 % RH. Based on the obtained stability study results, the following storage conditions of the product were established "Do not store above 25 °C, do not freeze" with proposed shelf life 2 years. This corresponds to the storage conditions of the reference product Diprivan, emulsion for injection or infusion.	

Decision in 331st meeting of Drug Registration Board:
Registration Board deferred the case for clarification of applied container closure system.

Proceeding of the case:
Firm has submitted reply with respect to observations of the DRB in 331st meeting, as under: -
"For submitted Section 1.5.4, 20 ml ampoules (05 ampoules in a pack) has been selected, the shift in packing of product from vials to ampoules has been made owing to stability data. The product in ampoules packing is stable and T18 as compared with drug product in vial packing.
Long term stability data of diprofol 1% for 24 months has been attached herewith "
Evaluator remarks:
The stability data submitted for propofol in ampoule packing for 24 month of shelf life has been found satisfactory. Now firm requested to consider ampoule packing for registration instead of vials.

Case is accordingly submitted before the Board for consideration.

Decision: Approved with 20ml ampoule (05 ampoules in a pack) as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

205.	**Name of the medicinal product to be imported:**	**Diprofol EDTA 20mg / ml (2%)** **Each 1ml of emulsion contains** **Propofol 20mg**
	Name, address of Applicant / Importer	**Bristol Mayer Biotech Pakistan** **Head Office Address:** **73-B, Guldasht Town, Zarrar Shaheed Road, Lahore – Cantt.**
	Details of Drug Sale License of importer	License No: 05-352-0068-029407D Address: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore – Cantt. Validity: 07-04-2027. Status: License to sell drugs as a distributor Renewal: N/A
	Name and address ofmarketing authorization holder(abroad)	Joint Stock Company "FARMAK" Address: 63, Kyrylivska Street, Kyiv, 04080 Ukraine.
	Name, address of manufacturer(s)	Name: Joint Stock Company "FARMAK" Address: 74, Kyrylivska St., Kyiv, 04080, Ukraine; 4, Chornomorska St., Kyiv, 04080, Ukraine.
	Name of exporting country	Ukraine
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP (Original & Legalized): Firm has submitted original, legalized CoPP Product License: UA/15942/01/01 Date of Issue: 16-11-2021 Date of Legalization: 31-07-2023 GMP validity: 13-12-2024 Issued by: State Service of Ukraine on Medicines & Drugs Control, 120-A Peremohy Avenue, Kyiv, Ukraine. 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.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization/Power of Attorney certificate from JSC FARMAK, a legal entity organized and existing under the laws of Ukraine registered with Commercial Register at the Registration No: 00481198 Tax Payer Registration No. in Ukraine: 3150525658 Date of Authorization: 04-07-2019 Details of entity authorized in Pakistan: Bristol Mayer Biotech Pakistan Head Office Address: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore – Cantt.
	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 ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 22829 Dated: 18-09-2023
	Details of fee submitted	PKR 150,000/-: 16-08-2023 Slip # 556606276638
	The proposed proprietary name / brand name	DIPROFOL EDTA 20mg/ml Emulsion for injection/infusion.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1 ml of emulsion contains: Propofol 20mg
	Pharmaceutical form of applied drug	Sterile emulsion for injection
	Pharmacotherapeutic Group of (API)	General Anesthesia
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack size	20 ml vial
	Proposed unit price	20 ml vial
	The status in reference regulatory authorities	MHRA approved formulation.
	For generic drugs (me-too status)	B.Braun formulation
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: Bachem S.A. Address: Route Du Simplon 22, 1895 Vionnaz, Switzerland.
	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)	Recommended EDQM storage conditions for unopened container: 5 ^{o}C ±3^{o}C
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Name: Diprivan® Manufacturer: Aspen Pharma Trading Ltd Ireland.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Al-tube with inner lacquer and tube sealing and screw cap PE
	Stability study data of drug product, shelf life and storage conditions	*Firm has submitted stability data vials with different pack sizes (20ml vials, 50ml vials & 100 ml vials) both at accelerated as well as long term stability conditions.* Accelerated Stability conditions: Temperature: 40 ± 2^{o}C Relative Humidity: 75 ± 5% Long term stability conditions Temperature: 30 ± 2^{o}C Relative Humidity: 75 ± 5%

Evaluation by PEC:

Section	Observations	Status
1.5.4	Please mention a single dosage form along with single pack size i.e. **Ampoule OR vial.** Multiple dosage form and multiple pack size of Ampoule and vials cannot be allowed in a single registration letter.	20 ml vials has been selected with a single pack size.
3.2.S.7	Please submit stability data of minimum 03 commercial scale batches of API conducted by	Certificate of suitability submitted for API issued by EDQM.

	drug substance manufacturer at Zone IV-A storage conditions.	
3.2.P.2	Please justify that how the Pharmaceutical equivalence studies of your drug product packed in vials and ampoule, a different primary container of drug product than prefilled syringes of **Diprivan 1% manufactured by Aspen Ireland.**	For pharmaceutical equivalence studies **Dprivan 1% & Diprivan2%** have been used as reference products. For our selected volume of 20ml vial, Disoprivan 1% 20ml vial Batch # RC20003C & Batch # RC 20007A Germany.
3.2.P.8	Please submit stability data of minimum 03 commercial scale batches of drug product with only one pack size **(20ml OR 50ml OR 100ml)**. a single pack size is allowed in a single application.	Firm has submitted only 12-month data for long term storage conditions for ZONE IV-A.

Explanation Letter

We, JSC «FARMAK» with legal address 63, Kyrylivska street, Kyiv, 04080, Ukraine would like to express our respect and to inform you about the stability studies of our product Diprofol EDTA 10 mg/mL or 20 mg/mL emulsion for injection/infusion.

We kindly confirm that the stability study of the drug product is performed in accordance with ICH Guideline Q1A (R2) Stability Testing of New Drug Substances and Products. Initial Long term stability studies were conducted under the conditions 30 ± 2 ºC / 75 ± 5% RH and at the time of the dossier submission to the Regulatory Authority of Pakistan, the product complied with all test parameters.

Later, it was discovered that in T18 the product does not meet the requirements according to the "Free fatty acids" indicator. Therefore, we provide information about 24 months of Diprofol EDTA 10 mg/mL or 20 mg/mL emulsion for injection/infusion stability studies under the conditions 25 ± 2°C / 60 ± 5 % RH. Based on the obtained stability study results, the following storage conditions of the product were established "Do not store above 25 °C, do not freeze" with proposed shelf life 2 years. This corresponds to the storage conditions of the reference product Diprivan, emulsion for injection or infusion.

Decision in 331st meeting of Drug Registration Board:

Registration Board deferred the case for clarification of applied container closure system.

Proceeding of the case:

Firm has submitted reply with respect to observations of the DRB in 331st meeting, as under: -

"For submitted Section 1.5.4, 20 ml ampoules (05 ampoules in a pack) has been selected, the shift in packing of product from vials to ampoules has been made owing to stability data. The product in ampoules packing is stable and T18 as compared with drug product in vial packing.

Long term stability data of diprofol 1% for 24 months has been attached herewith "

Evaluator remarks:

The stability data submitted for propofol in ampoule packing for 24 month of shelf life has been found satisfactory. Now firm requested to consider ampoule packing for registration instead of vials.

Case is accordingly submitted before the Board for consideration.

Decision: Approved with 20ml ampoule (05 ampoules in a pack) as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

206.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals Private Limited. 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore. (DML # 000150)**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited. 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore. (DML # 000150)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17599 (dated: 16-06-2022)
	Details of fee submitted	PKR 30,000/-: dated: 02-12-2021 (Invoice # 83478848)
	The proposed proprietary name / brand name	Ketarol Injection 50mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ketamine (as HCl)..... 50 mg (100mg/2ml)
	Pharmaceutical form of applied drug	Ampoule for injection
	Pharmacotherapeutic Group of (API)	General Anesthesia
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	05 ampoules of 2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*MHRA* approved formulation
	For generic drugs (me-too status)	Ketasol by M/s Indus Pharma
	GMP status of the Finished product manufacturer	Firm submitted inspection report dated 02-02-2023 GMP compliance "A" Liquid Sterile Injection (Psychotropic) Section. Liquid Injectable ampoule (psychotropic) section was granted by 30-05-2022 vide Letter No F. 1-38-91-Lic (Vol-II)
	Name and address of API manufacturer.	Ketamine HCl M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – khed, District – Ratnagiri, Maharashtra, India. GMP Certificate valid till 23-11-2024
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e Ketaral injection by M/s Par Pharmaceuticals by performing quality tests (appearance, identification, pH , Assay & sterility test).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	Ketamine HCl M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – khed, District – Ratnagiri, Maharashtra, India. GMP Certificate valid till 23-11-2024		
API Lot No.	SLL/KH/0619026		
Description of Pack (Container closure system)	Clear colorless and sterile solution for injection is supplied in USP type I 2ml clear amber glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	20000 ampoules	20000 ampoules	20000 ampoules
Manufacturing Date	02/2021	02/2021	02/2021
Date of Initiation	17/05/2021	17/05/2021	17/05/2021
No. of Batches	03		
Administrative Portion			
i.	Reference of previous approval of applications with stability	Not applicable	

	study data of the firm (if any)	
ii.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
iii.	Documents for the procurement of API with approval from DRAP (in case of import).	Ref. # 13452/2021/DRAP-AD-VI (I & E) **Dated** 20-01-2021 **Quantity:** 3000 gm
iv.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
v.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
vi.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Decision of 330th meeting of DRB:

Registration Board deferred the case for opinion of Division of Control Drugs, DRAP regarding:

i. Legal status for API (Ketamine HCl) imported before declaration as controlled drug and afterwards its consumption by Drug Product Manufacturer for Pharmaceutical Development & stability batches.

ii. Requirement of manufacturing area whether segregated Psychotropic facility required or not.

Remarks of the Evaluator:

- The firm has imported the ketamine API (03 kg) as per provided invoice, for production of three (03) trial batches on 20th January 2021. Trial batches were manufactured in 02/2021.
- Ketamine and its salts have been declared as "Psychotropic" vide SRO No. 1350(I)/2021 dated 15-10-2021.
- Liquid Injectable ampoule (psychotropic) section was granted by 30-05-2022 vide Letter No F. 1-38-91-Lic (Vol-II).
- Trial batch sizes needs clarification from firm.

Decision: Deferred for following:

- **Justify that 03 kgs of API is sufficient for the manufacturing of 03 batches of 20000 ampoules each**
- **Submission of BMRs for the said manufactured batches.**
- **Submission of No Objection Certificate from Ministry of Narcotics Control**

207.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Brookes Pharma Private Limited. 58-59 Sector 15, Korangi Industrial Area, Karachi (DML # 000275)**
	Name, address of Manufacturing site.	M/s Brookes Pharma Private Limited. 58-59 Sector 15, Korangi Industrial Area, Karachi **(DML # 000275)**
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**

	Dy. No. and date of submission	Dy. No. 10005 (dated: 13-04-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-02-2023 (Invoice # 814271949980)
	The proposed proprietary name / brand name	**Ketaflex Injection 50mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ketamine (as HCl)..... 50 mg
	Pharmaceutical form of applied drug	Ampoule for injection
	Pharmacotherapeutic Group of (API)	General Anesthesia
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	05 ampoules of 2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*MHRA* approved formulation
	For generic drugs (me-too status)	Ketasol by M/s Indus Pharma
	GMP status of the Finished product manufacturer	Central Licensing Board in its 277th meeting approved the renewal of DML including Injectable (Psychotropic) section.
	Name and address of API manufacturer.	**Ketamine HCl** M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – khed, District – Ratnagiri, Maharashtra, India. **GMP Certificate valid till 23-11-2024**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Stability study conditions**: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e Ketasol injection by M/s Indus** by performing quality tests (appearance, identification, pH , Assay & sterility test).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	**Ketamine HCl** M/s Supriya Life Science Ltd. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – khed, District – Ratnagiri, Maharashtra, India. **GMP Certificate valid till 23-11-2024**		
API Lot No.	SLL/KH/0618040		
Description of Pack (Container closure system)	2ml amber glass USP type I ampoule, further packed in unit pack containing 05 ampoules with PVC tray and insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**PD-T-010E1**	**PD-PS-OO4A1**	**PD-T-O43KO**
Batch Size	5.0 Litre	10 Litre	5.0 Litre
Manufacturing Date	06/2021	01/2021	11/2020
Date of Initiation	02/06/2021	18/01/2021	02/12/2020
No. of Batches	03		

Administrative Portion

i.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
ii.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
iii.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice # SLL/E/18-19/868 Dated 6/11/2018 Quantity : 3 kg
iv.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
v.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
vi.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Observations	Reply
3.2.P.2.3 Please justify that why Pharmaceutical	Ketasol has been chosen because it is a

	equivalence studies have been performed against a local brand **Ketasol** instead of Innovator brand	registered brand in Pakistan by DRAP. This was also supported by "WHO Annexure 8 ; guidance for the selection of comparator pharmaceutical product for equivalence assessment of interchangeable multisource"
	Please submit COA and approval documents of API import from DRAP for API LOT# SLL/KH/0618040.	Submitted

Decision of 330th meeting of DRB:

Registration Board deferred the case for opinion of Division of Control Drugs, DRAP regarding:

i. *Legal status for API (Ketamine HCl) imported before declaration as controlled drug and afterwards its consumption by Drug Product Manufacturer for Pharmaceutical Development & stability batches.*
ii. *Requirement of manufacturing area whether segregated Psychotropic facility required or not.*

Remarks of the Evaluator:

- The firm has imported the ketamine API (03kg) as per provided invoice vide Invoice # SLL/E/18-19/868 Dated 6/11/2018
- Trial batches were manufactured in 11/2020, 01/2021 & 06/2021.
- Ketamine and its salts have been declared as "Psychotropic" vide SRO No. 1350(I)/2021 dated 15-10-2021.
- Firm possess Liquid Injectable (psychotropic) section.
- Firm already possess registration of ketamine in 10 ml ampoule.

Decision: Approved subject to submission of No objection Certificate issued by Ministry of Narcotics Control

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

Item No. 06: Priority as per 257th meeting of Drug Registration Board

208.	**Name, address of Applicant / Importer**	**M/s Martin Dow Limited** **Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 595 Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: i. Plot # 32, Sec:16 K.I.A Karachi. ii. 1st floor, plot # 211, Sec: 23 K.I.A Karachi iii. Plot # 116, Sec: 15 K.I.A Karachi. Validity: 16-06-2024 Status: VALID
	Name and address of marketing authorization holder (abroad)	**DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL Sicil No: 70061 **Turkey.**
	Name, address of manufacturer(s)	**DEVA HOLDING A.S.** Cerkezkoy Organize Sanayi Bölgesi, Karaağaç Mah. Fatih bulvarı No:26, Kapaklı – TEKİRDAĞ **Turkey.**
	Name of exporting country	**Turkey**

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 14th March 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2023/796) dated 27-02-2023 issued by Turkish Medicines and Medical Device Agency. The CoPP specifies free sale status of the product in country of export along with its availability. The certifying authority arrange for periodic inspection which validity is 03 years. • **GMP Certificate # TR/GMP/2022/292:** ✓ Issued on 10-11-2022 ✓ Validity: 03 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP for production of anticancer (oncological) lyophilized injectable vials.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL **Turkey.** The letter certifies that the drug product manufacturer in Turky authorizes **M/s Martin Dow Limited** **Address:** Plot # 37, Sector 19, Korangi Industrial Area, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **Vopazzi Tablet 200mg** in Pakistan. The letter was issued on 02.05.2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 13644 Dated: 01st June 2023
	Details of fee submitted	PKR 150000/-: 09th May 2023 Slip # 809052338008
	The proposed proprietary name / brand name	**Vopazzi Tablet 200 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Pazopanib HCl 216.7mg equivalent to Pazopanib..... 200 mg

	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent *(Protein kinase inhibitor)*
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Votrient®** by Novartis UK MHRA approved (PLGB 00101/1160)
	For generic drugs (me-too status)	Votrient by Novartis (Pakistan) Limited *(import)* (Reg. # 069534)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	**DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL Sicil No: 70061 **Turkey.** **GMP Validity:** 09-01-2026
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C /RH ± 75°C for 06 months. **Real time:** 25 ± 2°C / RH 60°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	**Name:** Votrient® 200mg Tablet **Manufacturer**: Novartis EuroPharm Ltd.

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Transparent PVC/Aclar and aluminum foil blister.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.
Evaluation by PEC:		
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.		
209.	**Name, address of Applicant / Importer**	**M/s Martin Dow Limited** **Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 595 Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: iv. Plot # 32, Sec:16 K.I.A Karachi. v. 1st floor, plot # 211, Sec: 23 K.I.A Karachi vi. Plot # 116, Sec: 15 K.I.A Karachi. Validity: 16-06-2024 Status: VALID
	Name and address of marketing authorization holder (abroad)	**DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL Sicil No: 70061 **Turkey.**
	Name, address of manufacturer(s)	**DEVA HOLDING A.S.** Cerkezkoy Organize Sanayi Bölgesi, Karaağaç Mah. Fatih bulvarı No:26, Kapaklı – TEKİRDAĞ **Turkey.**
	Name of exporting country	**Turkey**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Original & Legalized</u>** **Date of Legalization:** 14th March 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2023/797) dated 27-02-2023 issued by Turkish Medicines and Medical Device Agency. The CoPP specifies free sale status of the product in country of export along with its availability. The certifying authority arrange for periodic inspection which validity is 03 years. • **GMP Certificate # TR/GMP/2022/292:** ✓ Issued on 10-11-2022 ✓ Validity: 03 years from date of issuance.

		✓ Certificate confirms that drug manufacturer complies with the requirement of GMP for production of anticancer (oncological) lyophilized injectable vials.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL **Turkey.** The letter certifies that the drug product manufacturer in Turky authorizes **M/s Martin Dow Limited** **Address:** Plot # 37, Sector 19, Korangi Industrial Area, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **Vopazzi Tablet 200mg** in Pakistan. The letter was issued on 02.05.2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 13645 Dated: 01st June 2023
	Details of fee submitted	PKR 150000/-: 09th May 2023 Slip # 45281450014
	The proposed proprietary name / brand name	**Vopazzi Tablet 400 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Pazopanib HCl 433.40 mg equivalent to Pazopanib..... 400 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent *(Protein kinase inhibitor)*
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	60's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Votrient®** by Novartis UK MHRA approved (PLGB 00101/1160)

	For generic drugs (me-too status)	Votrient by Novartis (Pakistan) Limited *(import)* (Reg. # 069535)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	**DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL Sicil No: 70061 **Turkey.** **GMP Validity:** 09-01-2026
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C /RH ± 75°C for 06 months. **Real time:** 25 ± 2°C / RH 60°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	**Name:** Votrient® 400mg Tablet **Manufacturer**: Novartis EuroPharm Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Transparent PVC/Aclar and aluminum foil blister.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months

		Temperature: 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.
Evaluation by PEC:		
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.		
210.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd Address: Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0065-016174D Address: Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore, Pakistan. Address of Godown: NA Validity: 06.02.2024 Status: VALID
	Name and address of marketing authorization holder (abroad)	**Beacon Pharmaceuticals Limited** **Plant Address:** Kathali, Bhaluka, Mymensingh, Bangladesh. **Office Address:** 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	**Beacon Pharmaceuticals Limited** **Plant Address:** Kathali, Bhaluka, Mymensingh, Bangladesh.
	Name of exporting country	**Bangladesh**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 28th August 2022 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. DA/6-110/2016) dated 03-08-2022 issued by Directorate General of Drug Administration, Dhaka, Bangladesh. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 2 years • **GMP:** The firm has also submitted Original legalized GMP No. DA/6-110/06/5027, inspection of this manufacturer was conducted on 14-03-2021 and it is considered that it complies with the requirements of Cgmp, Valid for two (02) years after date of issue.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **Beacon Pharmaceuticals Limited** **Office Address:** 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh. The letter certifies that "M/s Himmel Pharmaceuticals (Pvt.) Ltd," with address

		"Ground Floor,6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan, Lahore" is their exclusive agent to register and market "**Pazonix 400 mg Tablet**" in the territory of Pakistan. The letter was issued on 14-08-2022.
	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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 4210 Dated: 14th February 2023
	Details of fee submitted	PKR 150000/-: 24th January 2023 Slip # 96556669
	The proposed proprietary name / brand name	**PAZONIX 400 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Pazopanib HCl 433.332 mg equivalent to Pazopanib..... 400 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent *(Protein kinase inhibitor)*
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	HDPE bottle (each bottle contains 60 tablets)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Votrient®** by Novartis UK MHRA approved (PLGB 00101/1160)
	For generic drugs (me-too status)	Votrient by Novartis (Pakistan) Limited *(import)* (Reg. # 069535)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** Acebright (India) Pharma Pvt. Ltd. **Address:** No. 77D & 116/117, KIADB Industrial Area, Jigani, Bangalore, Karataka, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2ºC / RH 75 ± 5% for 06 months. **Real time:** 25ºC ± 2ºC / RH 60 ± 5% for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** Votrient® 400mg Tablet **Manufacturer**: Novartis EuroPharm Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colorless glass 6R vial, hydrolytic class type I, closed with a suitable rubber stopper and an aluminum crimp cap with a plastic flip off.
	Stability study data of drug product, shelf life and storage conditions	Stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.

Evaluation by PEC:

During initial scrutiny, following observations / shortcomings were observed:

Section	Observations	Reply of the firm
1.3.4	• Please submit a within use-by date / valid GMP certificate for the manufacturing facility of Beacon Pharmaceuticals Limited, Dhaka Bangladesh, for manufacturing of antineoplastic formulation of Pazopanib in oral dosage form (film coated Tablets). • Please submit information / documentation regarding manufacturing facility for antineoplastic agent to be manufactured General facility **OR** in a dedicated facility as per definition of WHO guidelines for good manufacturing practices for cytotoxic drugs ?	Submitted

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

Item No 07: Form 5 cases

211.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577) 21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Tablet Galant 4 mg
	Composition	Each film coated tablet contains: Galantamine (as hydro-bromide) ……. 4 mg
	Diary No. Date of R& I & fee	Dy. No 8388 dated 14-09-2010 Rs. 8,000/- *Photocopy* Dy. No 30989 dated 20/01/2020 *(Duplicate)* Rs. 12000/-
	Pharmacological Group	Acetylcholinesterase Inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada approved **Reminyl®**
	Me-too status	**Reminyl®** (import)
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
212.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577) 21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Tablet Vitrin 500 mg
	Composition	Each film coated tablet contains: Vigabatrin..... 500 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 17942 dated 17-07-2023* Dy. No 10685 dated 16-11-2010 *(verified)* Rs. 8,000/- *(photocopy)* Dy. No 17942 dated 17/07/2020 Rs. 12000/- dated 01-01-2020
	Pharmacological Group	Acetylcholinesterase Inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved SABRIL®
	Me-too status	Evolep tablet by Evolution Pharmaceuticals
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
213.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577) 21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**

	Brand Name +Dosage Form + Strength	Daplin – B Gel
	Composition	Each one gram of gel contains: Adapalene..... 01 mg (0.1% w/w) Benzoyl Peroxide .....25 mg (2.5% w/w)
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 17943 dated 17-07-2023* Dy. No 9728 dated 18-10-2010 *(verified)* Rs. 8,000/- *(Photocopy)* Dy. No 17943 dated 17/07/2020 Rs. 12000/- dated 01-01-2020 *(Photocopy)*
	Pharmacological Group	Anti-Acne preparations for topical use
	Type of Form	Form 5
	Finished Product Specification	Innovator Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation (PL 10590/0057)
	Me-too status	A product of Pharmatec
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
214.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577)** **21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Permit Cream
	Composition	Each one gram of cream contains: Permethrin ……. 5% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 17947 dated 17-07-2023* Dy. No 8656 dated 23-09-2010 *(verified)* Rs. 8,000/- *(Photocopy)* Rs. 12000/- dated 23-11-2018 *(photocopy)*
	Pharmacological Group	Anti-Scabies
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation (PL 10590/0057)
	Me-too status	Lotrix by GSK
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
215.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577)** **21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Permit Lotion
	Composition	Each one gram of Lotion contains: Permethrin ……. 5% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 17946 dated 17-07-2023* Dy. No 8685 dated 23-09-2010 *(verified)* Rs. 8,000/- *(Photocopy)* Rs. 12000/- dated 28-11-2018 *(Photocopy)*

	Pharmacological Group	Anti-Scabies
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	KWELLADA-P LOTION (Health Canda)
	Me-too status	Skab Lotion by Shaigan
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
216.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577)** **21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Benzcin Gel
	Composition	Each one gram of Gel contains: Clindamycin (as phosphate) ……. 1% w/w Benzoyl Peroxide .....5% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 17941 dated 17-07-2023* Dy. No 9726 dated 18-10-2010 *(verified)* Rs. 8,000/- *(Photocopy)* Rs. 12000/- dated 28-11-2018 *(Photocopy)*
	Pharmacological Group	Keratolytic /antibiotics
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia
	Me-too status	Skab Lotion by Shaigan
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	Firm has to adopt BP specification as monograph available along with prescribed free for change in specifications.
	Decision: Deferred for submission of data as per guidance issued vide letter No. 9-2/2022-PEC dated 18.12.2023 for proposed "manufacturer's specifications".	
217.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577)** **21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Enzoy Gel 5%
	Composition	Each one gram of Gel contains: Benzoyl Peroxide .....5% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 17945 dated 17-07-2023* Dy. No 9725 dated 18-10-2010 Rs. 8,000/- *(Form 5)* Rs. 12000/- dated 30-11-2018
	Pharmacological Group	Antibacterials
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Panoxyl by GSK

	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
218.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577) 21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Enzoy Gel 10%
	Composition	Each one gram of Gel contains: Benzoyl Peroxide .....10% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 17944 dated 17-07-2023* Dy. No 9724 dated 18-10-2010 Rs. 8,000/- *(Form 5)* Rs. 12000/- dated 28-11-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Benoxyl Gel by Glitz Pharma
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
219.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd (DML # 000577) 21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Brand Name +Dosage Form + Strength	Lodical Tablet 0.5 mcg
	Composition	Each tablet contains: Alfacalcidol.....0.5 mcg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 27629 dated 17-07-2023* Dy. No 10679 dated 16-11-2010 Rs. 8,000/- *(Form 5)* Rs. 12000/- dated 28-11-2018
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alfacalcidol tablet 0.5mcg PMDA Japan approved
	Me-too status	Locally registered
	GMP status	GMP certificate issued on the basis of inspection report conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
220.	**Name and address of manufacturer / Applicant**	**M/s English Pharmaceuticals Industries. (DML # 000339) Indus Link Katarband Road Thokar Niaz Beg, Multan Road Lahore.**
	Brand Name +Dosage Form + Strength	Tablet Acetrdol

	Composition	Each film coated tablet contains: Paracetamol..... 325 mg Tramadol HCl..... 37.5 mg
	Diary No. Date of R& I & fee	Dy. No 7801 dated 20-08-2010 Rs. 8,000/- *(Form 5)* Dy. No 41 dated 07/07/2015 Rs. 12000/- dated 06-07-2015
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	*USFDA approved* **Ultracet®** by Janssen
	Me-too status	**Tonoflex-p** by M/s Sami.
	GMP status	GMP certificate validity: 14-07-2024
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board	
221.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals (DML # 000340) 216-217, I-10/3, Industrial Area Islamabad**
	Brand Name +Dosage Form + Strength	Tablet Favour 2 mg
	Composition	Each uncoated tablet contains: iloperidone..... 2 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 28184 dated 06-12-2023* Dy. No 1014 dated 06-01-2011 *(verified)* Rs. 8,000/- *(Photocopy)* Dy. No dated 17-02-2017 Rs. 12000/- dated 17-02-2017 *(Photocopy)*
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	*USFDA approved* **Fanapt®** by Vanda.
	Me-too status	Ilodon 2mg tablets by Genix
	GMP status	GMP certificate issued by DRAP Validity: 11-08-2025
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board	
222.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals (DML # 000340) 216-217, I-10/3, Industrial Area Islamabad**
	Brand Name +Dosage Form + Strength	Tablet Favour 4 mg
	Composition	Each uncoated tablet contains: iloperidone..... 4 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 28185 dated 06-12-2023* Dy. No 1006 dated 06-01-2011 *(verified)* Rs. 8,000/- *(Photocopy)* Dy. No dated 17-02-2017 Rs. 12000/- dated 17-02-2017 *(Photocopy)*
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	*USFDA approved* **Fanapt®** by Vanda.
	Me-too status	Ilodon 4mg tablets by Genix
	GMP status	GMP certificate issued by DRAP Validity: 11-08-2025
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
223.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals (DML # 000340) 216-217, I-10/3, Industrial Area Islamabad**
	Brand Name +Dosage Form + Strength	Tablet Favour 6 mg
	Composition	Each uncoated tablet contains: iloperidone..... 6 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 28186 dated 06-12-2023* Dy. No 1016 dated 06-01-2011 *(verified)* Rs. 8,000/- *(Photocopy)* Dy.No dated 17-02-2017 Rs. 12000/- dated 17-02-2017 *(photocopy)*
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	*USFDA approved* **Fanapt®** by Vanda.
	Me-too status	Ilodon 6mg tablets by Genix
	GMP status	GMP certificate issued by DRAP Validity: 11-08-2025
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
224.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals (DML # 000340) 216-217, I-10/3, Industrial Area Islamabad**
	Brand Name +Dosage Form + Strength	Tablet Favour 12 mg
	Composition	Each uncoated tablet contains: iloperidone..... 12 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 28187 dated 06-12-2023* Dy. No 1012 dated 06-01-2011 *(verified)* Rs. 8,000/- *(photocopy)* Dy. No 41 dated 07/07/2015 Rs. 12000/- dated 17-02-2017 *(photocopy)*
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	*USFDA approved* **Fanapt®** by Vanda.
	Me-too status	Ilodon 12mg tablets by Genix
	GMP status	GMP certificate issued by DRAP Validity: 11-08-2025
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
225.	**Name and address of manufacturer / Applicant**	**M/s Medisure Laboratories Pakistan (Pvt) Ltd. (DML # 000503)**

		A-115 S.I.T.E Super Highway Karachi.
	Brand Name +Dosage Form + Strength	Tablet Dicsium 50 mg
	Composition	Each film coated tablet contains: Diclofenac Potassium..... 50 mg
	Diary No. Date of R& I & fee	Dy. No 44 dated 08-02-2011 Rs. 8,000/- *(Form 5)* Rs. 12000/- dated 11-04-2016
	Pharmacological Group	NSAIDS
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulations
	Me-too status	Cicota 50 mg tablets by Linz Pharmaceuticals
	GMP status	GMP certificate issued by DRAP Validity: 15-02-2025
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
226.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714)** **Plot No. 2 Street No. 4 National Industrial Zone Rawat.**
	Brand Name +Dosage Form + Strength	Tablet Mecobin 500 mcg
	Composition	Each film coated tablet contains: Mecobalamin..... 500 mcg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 7075 dated 10-03-2023* Dy. No 2795 dated 23-06-2011 (*verified)* Rs. 8,000/- *(Photocopy)* *Rs. 20000/- dated 27-01-2020 (Photocopy)*
	Pharmacological Group	Vitamins supplement
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Registered in Pakistan
	GMP status	GMP certificate issued by DRAP Validity: not provided
	Remarks of the Evaluator[3].	• Firm has changed the dosage form of applied formulation from capsule to tablet by submitting differential fee of PKR 20000/- on 27-01-2020 however, the complete fee of PKR 20000/- required for FORM 5 application is still deficient of PKR 12000/- while the differential fee is also PKR30000/- • Formulation in film coated not verified from RRA countries. • USP specification not found for this dosage form as claimed by the firm.
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
227.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714)** **Plot No. 2 Street No. 4 National Industrial Zone Rawat.**
	Brand Name +Dosage Form + Strength	Cromiton Cream

	Composition	Each gram of cream contains: Crotamiton..... 10% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 7078 dated 10-03-2023* Dy. No 2485 dated 20-06-2011 *(verified)* Rs. 8,000/- *(Phtocopy)* Rs. 12000/- dated 27-01-2020 *(Photocopy)*
	Pharmacological Group	Antipruritics
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Eurax Cream
	Me-too status	Registered in Pakistan for Zafa Pharma
	GMP status	GMP certificate issued by DRAP on the basis of inspection report dated 26-10-2021
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
228.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714)** **Plot No. 2 Street No. 4 National Industrial Zone Rawat.**
	Brand Name +Dosage Form + Strength	Medifax Plus ointment
	Composition	Each gram of ointment contains: Polymixine B sulphate… …. 10000 units Bacitracin Zinc .....500 units Lignocain..... 40 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 7072 dated 10-03-2023* Dy. No 2485 dated 20-06-2011 *(verified)* Rs. 8,000/- *(Photocopy)* Rs. 12000/- dated 27-01-2020 *(Photocopy)*
	Pharmacological Group	Antipruritics
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Polyfax Plus ointment
	GMP status	GMP certificate issued by DRAP on the basis of inspection report dated 26-10-2021
	Remarks of the Evaluator[3].	
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
229.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714)** **Plot No. 2 Street No. 4 National Industrial Zone Rawat.**
	Brand Name +Dosage Form + Strength	Betamed 0.1% Cream
	Composition	Each gram of cream contains: Betamethasone (as Valerate) …. 0.1% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 7077 dated 10-03-2023* Dy. No 2491 dated 20-06-2011 *(verified)* Rs. 8,000/- *(Photocopy)* Rs. 12000/- dated 27-01-2020 *(Photocopy)*
	Pharmacological Group	ATC code D07AC Corticosteroids, potent (group III)

	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Registered for Tas Pharma
	GMP status	GMP certificate issued by DRAP on the basis of inspection report dated 26-10-2021
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
230.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714)** **Plot No. 2 Street No. 4 National Industrial Zone Rawat.**
	Brand Name +Dosage Form + Strength	Metasone Ointment
	Composition	Each gram of ointment contains: mometasone (as furoate) …. 0.1% w/w
	Diary No. Date of R& I & fee	Dy. No 2489 dated 20-06-2011 (Duplicate) Rs. 8,000/- *(Form 5)* Rs. 12000/- dated 27-01-2020
	Pharmacological Group	ATC code D07AC Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Metavate by Global Pharma
	GMP status	GMP certificate issued by DRAP on the basis of inspection report dated 26-10-2021
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
231.	**Name and address of manufacturer / Applicant**	**M/s Medera Pharmaceuticals (Pvt) Ltd. (DML # 000714)** **Plot No. 2 Street No. 4 National Industrial Zone Rawat.**
	Brand Name +Dosage Form + Strength	Osteorin Capsule 50 mg
	Composition	Each hard gelatin capsule contains: Diacerin.....50 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 7073 dated 10-03-2023* Dy. No 2489 dated 20-06-2011 *(verified)* Rs. 8,000/- *(Photocopy)* Rs. 12000/- dated 27-01-2020 *(Photocopy)*
	Pharmacological Group	Anthraquinones
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Rein Capsule by SJ&G Fazul Ellahie
	GMP status	GMP certificate issued by DRAP on the basis of inspection report dated 26-10-2021
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	

232.	**Name and address of manufacturer / Applicant**	**M/s Caraway Pharmaceuticals (DML # 000629) Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat.**
	Brand Name +Dosage Form + Strength	Celco-cib 200 mg Capsule
	Composition	Each hard gelatin capsule contains: Celecoxib..... 200 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 24882 dated 12-10-2023* Dy. No 3039 dated 20-01-2011 Rs. 8,000/- *(Form 5)* Rs. 12000/- dated 24-04-2015
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	A product of Medipak
	GMP status	Last inspection conducted on 22-02-2022. Tablet (General) Section
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
233.	**Name and address of manufacturer / Applicant**	**M/s Caraway Pharmaceuticals (DML # 000629) Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat.**
	Brand Name +Dosage Form + Strength	Movit 0.1% Cream
	Composition	Each 100gm of cream contains: Mometasone Furoate ..... 0.1 % w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 7079 dated 10-03-2023* Dy. No 6777 dated 19-07-2010 *(verified)* Rs. 8,000/- *(Photocopy)* Rs. 12000/- dated 20-05-2013 *(Photocopy)*
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Metavate by Global
	GMP status	Last inspection conducted on 22-02-2022. Cream Ointment Section
	Remarks of the Evaluator[3].	Deferred in 240th DRB meeting for segregated section approval letter.
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
234.	**Name and address of manufacturer / Applicant**	**M/s Caraway Pharmaceuticals (DML # 000629) Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat.**
	Brand Name +Dosage Form + Strength	Valcozone Tablet
	Composition	Each film coated tablet contains: Valaciclovir Hcl 500mg
	Diary No. Date of R& I & fee	Dy. No 6774 dated 19-07-2010 Rs. 8,000/- *(Form 5)*

		Rs. 12000/- dated 20-05-2013
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Valtrex by GSK
	GMP status	Last inspection conducted on 22-02-2022. Tablet General Setion
	Remarks of the Evaluator[3].	Deferred in 240th DRB meeting for clarification regarding measures taken by the firm for personnel safety. Now firm has submitted the SOPs and details of Personal protective equipment.
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
235.	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals (Pvt) Ltd. (DML # 000349) Plot No. C-i-20, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Safeplex Syrup
	Composition	Each 4ml contains Thiamine Hydrochloride .....2 mg Riboflavin Sodium Phosphate …. 2 mg Niacinamide .....10.00 mg Pyridoxine Hydrochloride..... 0.2 mg D-panthenol..... 2 mg Choline .....20 mg Inositol..... 10 mg Cyanocobalamin..... 5mcg
	Diary No. Date of R& I & fee	Dy. No 8794 dated 27-02-2019 Rs. 20,000/- dated 25-02-2019
	Pharmacological Group	Vitamin supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation Vigranon B syrup not matching completely.
	Me-too status	Lederplex syrup
	GMP status	Last inspection conducted on 19-09-2022. Liquid syrup (General) Section
	Remarks of the Evaluator[3].	RRA not confirmed
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
236.	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals (Pvt) Ltd. (DML # 000349) Plot No. C-i-20, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Safetivini Plus Syrup
	Composition	Each 15ml contains Thiamine Hydrochloride .....0.6 mg Pyridoxine Hydrochloride..... 10 mg Cyanocobalamin..... 0.0010 mg Nicotinamide..... 10 mg Calcium Lactate.....570 mg Magnesium sulphate..... 61.5 mg Maganese..... 3.15mg Riboflavin Sodium Phosphate..... 0.9 mg

	Diary No. Date of R& I & fee	Dy. No 8795 dated 27-02-2019 Rs. 20,000/- dated 25-02-2019
	Pharmacological Group	Vitamin supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Santevini plus Syrup ***(not verified)***
	Me-too status	Santevini plus Syrup GSK
	GMP status	Last inspection conducted on 19-09-2022. Liquid syrup (General) Section
	Remarks of the Evaluator[3].	RRA not confirmed
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
237.	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals (Pvt) Ltd. (DML # 000349) Plot No. C-i-20, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Megaday Syrup
	Composition	Each 5ml contains Vitamin A..... 3000 IU Vitamin D..... 400 IU Thiamine HCl..... 1.5 mg Riboflavin..... 1.2 mg Ascorbic Acid..... 50mg Nicotinamide..... 10 mg Pyridoxine HCl..... 1 mg Cyanocobalamin..... 3 mcg Panthenol..... 5 mg Iron .....3 mg Iodine..... 75 mcg Calcium .....40 mg Phosphorous .....43 mg Manganese..... 0.5 mg Magnesium..... 3 mg Zinc ..... 0.5 mg Choline .....5 mg Inositol..... 5 mg
	Diary No. Date of R& I & fee	Dy. No 8792 dated 27-02-2019 Rs. 20,000/- dated 25-02-2019
	Pharmacological Group	Vitamin supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vidalyn – m syrup by Abbott ***(not verified)***
	Me-too status	Vidalyn – m syrup by Abbott
	GMP status	Last inspection conducted on 19-09-2022. Liquid syrup (General) Section
	Remarks of the Evaluator[3].	RRA not confirmed
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
238.	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals (Pvt) Ltd. (DML # 000349) Plot No. C-i-20, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Ferroton Syrup
	Composition	Each 100ml contains Ferric Ammonium Citrate .....900 mg Folic Acid..... 10 mg

		Thiamine HCl..... 20 mg Pyridoxine HCl..... 40 mg Nicotinamide.....200 mg Cyanocobalamin..... 360 mcg
	Diary No. Date of R& I & fee	Dy. No 8793 dated 27-02-2019 Rs. 20,000/- dated 25-02-2019
	Pharmacological Group	Vitamin supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	***(not verified)***
	Me-too status	Vitaglobin syrup by swiss pharma
	GMP status	Last inspection conducted on 19-09-2022. Liquid syrup (General) Section
	Remarks of the Evaluator[3].	RRA not confirmed
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
239.	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals (Pvt) Ltd. (DML # 000349) Plot No. C-i-20, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Zyme B Plus Syrup
	Composition	Each 5ml contains Diastase .....135 mg Pepsin .....50 mg Papain.....50 mg Thiamine HCl..... 5 mg Riboflavin..... 2 mg Pyridoxine HCl..... 2 mg Nicotinamide .....20 mg Cyanocobalamin..... 5 mcg Calcium D-Pentothenate .....1 mg
	Diary No. Date of R& I & fee	Dy. No 8796 dated 27-02-2019 Rs. 20,000/- dated 25-02-2019
	Pharmacological Group	Vitamin supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	***(not verified)***
	Me-too status	Eplazyme syrup by EPLA
	GMP status	Last inspection conducted on 19-09-2022. Liquid syrup (General) Section
	Remarks of the Evaluator[3].	RRA not confirmed
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
240.	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals (Pvt) Ltd. (DML # 000349) Plot No. C-i-20, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Dayline Syrup
	Composition	Each 5ml contains Vitamin A..... 3000 IU Vitamin D..... 400 IU Thiamine HCl..... 1.5 mg Riboflavin..... 1.2 mg Pyridoxine HCl..... 1 mg Cyanocobalamin..... 3 mcg Ascorbic Acid..... 50mg

		Nicotinamide ..... 10 mg
	Diary No. Date of R& I & fee	Dy. No 8791 dated 27-02-2019 Rs. 20,000/- dated 25-02-2019
	Pharmacological Group	Vitamin supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	***(not verified)***
	Me-too status	Vidalyn syrup by Abbott
	GMP status	Last inspection conducted on 19-09-2022. Liquid syrup (General) Section
	Remarks of the Evaluator[3].	RRA not confirmed
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
241.	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals (Pvt) Ltd. (DML # 000349) Plot No. C-i-20, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	SafeVit Syrup
	Composition	Each 5ml contains Thiamine HCl..... 4.16 mg Riboflavin..... 1.66 mg Pyridoxine HCl..... 1 mg Niacinamide .....18 mg D-penthenol..... 2.50 mg Cyanocobalamin..... 8.33 mcg Ascorbic Acid..... 75mg Inositol..... 5 mg Lysine monohydrate…..... 33.33 mg
	Diary No. Date of R& I & fee	Dy. No 8790 dated 27-02-2019 Rs. 20,000/- dated 25-02-2019
	Pharmacological Group	Vitamin supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	***(not verified)***
	Me-too status	Lysovit syrup
	GMP status	Last inspection conducted on 19-09-2022. Liquid syrup (General) Section
	Remarks of the Evaluator[3].	RRA not confirmed
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
242.	**Name and address of manufacturer / Applicant**	**M/s CCL Pharmaceuticals (Pvt) Ltd. (DML # 000052) 62 Industrial Estate Kot Lakhpat Lahore.**
	Brand Name +Dosage Form + Strength	Terbi Tablet 250 mg
	Composition	Each tablet contains Terbinafine (as HCl)..... 250 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 13486 dated 16-06-2020* Dy. No 6993 dated 22-07-2010 *(verified)* Rs. 8,000/- dated 27-07-2010 *(Photocop)* Rs. 20,000/- dated 28-01-2020 *(Photocopy)*
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Lamisil GSK
	GMP status	Inspection report submitted – section GMP compliant
	Remarks of the Evaluator[3].	
	Decision: Approved. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
243.	**Name and address of manufacturer / Applicant**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad**
	Brand Name +Dosage Form + Strength	Capsule Higab 300 mg
	Composition	Each hard gelatin Capsule contains Pregabalin..... 300 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 27630 dated 29-09-2022* Dy. No 3177dated 04-03-2011 Rs. 8,000/- dated 04-03-2011 Rs. 12,000/- dated 07-11-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Lamisil GSK
	GMP status	Inspection report submitted – section GMP compliant
	Remarks of the Evaluator[3].	Firm needs to follow BP specifications as monograph available now and to submit prescribed fee for change in specification.
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
244.	**Name and address of manufacturer / Applicant**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhupura Road Faisalabad**
	Brand Name +Dosage Form + Strength	Tablet Linzo 400 mg
	Composition	Each film coated tablet contains Linezolid .....400 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 27629 dated 29-09-2022* Dy. No 2247dated 15-04-2010 Rs. 8,000/- dated 15-04-2010 Rs. 12,000/- dated 15-10-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved formulation
	Me-too status	Ecasil 400 mg Tablet by Sami Pharma
	GMP status	Inspection report submitted – section GMP compliant
	Remarks of the Evaluator[3].	Firm needs to follow USP specifications as monograph available now and to submit prescribed fee for change in specification.
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
245.	**Name and address of manufacturer / Applicant**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616)**

		19-Km Sheikhupura Road Faisalabad
	Brand Name +Dosage Form + Strength	Tablet Linzo 600 mg
	Composition	Each film coated tablet contains Linezolid .....600 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 27631 dated 29-09-2022* Dy. No 2248 dated 15-04-2010 Rs. 8,000/- dated 15-04-2010 Rs. 12,000/- dated 15-10-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved formulation
	Me-too status	Ecasil 600 mg Tablet by Sami Pharma
	GMP status	Inspection report submitted – section GMP compliant
	Remarks of the Evaluator[3].	Firm needs to follow USP specifications as monograph available now and to submit prescribed fee for change in specification.
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
246.	**Name and address of manufacturer / Applicant**	**M/s Dr. Raza Pharma (DML # 000389) Road B-4 P.No 44-C Indus: Estate Jamrud Road Peshawr.**
	Brand Name +Dosage Form + Strength	Tablet Fvonik 25 mg
	Composition	Each tablet contains Levosulpride..... 25 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 6406 dated 06-03-2023* Dy. No. dated 08-04-2011 *(verified)* Rs. 8,000/- dated 04-03-2011 *(Photocopy)* Rs. 12,000/- dated 18-09-2017 *(Photocopy)*
	Pharmacological Group	Selective antagonist of dopamine D2 receptor activity
	Type of Form	Form 5
	Finished Product Specification	Manufcaturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved.
	Me-too status	Sulvoric 25mg Tablet by M/s High-Q (Reg#070484)
	GMP status	Latest GMP status required
	Remarks of the Evaluator[3].	Firm needs to submit inspection report conducted within last 03 years OR fresh / valid GMP certificate.
	Decision: Deferred for the submission section approval from Licensing Division and the GMP certificate or GMP inspection report during the last 3 years. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
247.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan (Pvt) Ltd. (DML # 000051) 20 Km Ferozepur Road Lahore.**
	Brand Name +Dosage Form + Strength	Tramic 500 mg Injection
	Composition	Each 5ml of solution in ampoules contains Tranexamic acid.....500 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 18012 dated 17-07-2023*

		Dy. No. 17185 dated 05-10-2017 *(Verified)* Rs. 20,000/- dated 02-10-2017 *(photocopy)*
	Pharmacological Group	Antihemorrhagics
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Transamin by Hilton
	GMP status	Latest GMP status required
	Remarks of the Evaluator[3].	
	Decision: Deferred for the submission section approval from Licensing Division and the GMP certificate or GMP inspection report during the last 3 years. Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
248.	**Name and address of manufacturer / Applicant**	**M/s Care Pharmaceuticals** **(DML # 0000563)** **8-Km Thokar Raiwind Road Lahore.**
	Brand Name +Dosage Form + Strength	Care Saline Nasal Drops
	Composition	Each ml contains Sodium Chloride .....% w/v
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 7077 dated 10-03-2023* Dy. No. 8974dated 30-09-2010 *(verified)* Rs. 8000/- dated 30-09-2010 *(Photocopy)* Rs. 12000/- dated 08-03-2013 *(Photocopy)*
	Pharmacological Group	For nasal congestion
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	OTC product in USA
	Me-too status	Salinas drops by Xennon
	GMP status	Latest GMP status required
	Remarks of the Evaluator[3].	
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
249.	**Name and address of manufacturer / Applicant**	**M/s Stanley Pharmaceuticals (Pvt) Ltd.** **(DML # 0000434)** **Plot No. 84-B Industrial Estate Jamrud Road Peshawar.**
	Brand Name +Dosage Form + Strength	Histam Syrup
	Composition	Each 5 ml contains Pheniramine Maleate..... 15 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 6385 dated 07-03-2023* Dy. No. dated 18-03-2016 Rs. 20000/- dated 18-03-2016 *(Photocopy)*
	Pharmacological Group	Anti-allergic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Avil syrup
	GMP status	Latest GMP validity: 27-07-2024
	Remarks of the Evaluator[3].	
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	

250.	**Name and address of manufacturer / Applicant**	**M/s Stanley Pharmaceuticals (Pvt) Ltd. (DML # 0000434)** **Plot No. 84-B Industrial Estate Jamrud Road Peshawar.**
	Brand Name +Dosage Form + Strength	Orowash Mouth wash
	Composition	Each 100 ml contains Benzydamine HCl .....0.15 gm Chlorhexidine Gluconate..... 0.20 gm
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 6386 dated 07-03-2023* Dy. No. dated 18-03-2016 Rs. 20000/- dated 18-03-20163 *(Photocopy)*
	Pharmacological Group	Mouth wash
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Enziclor mouthwash
	GMP status	Latest GMP validity: 27-07-2024
	Remarks of the Evaluator[3].	
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	
251.	**Name and address of manufacturer / Applicant**	**M/s Libra (Pvt) Ltd. (DML # 0000369)** **77 Industrial Estate Hayatabad Peshawar.**
	Brand Name +Dosage Form + Strength	Tablet ENR-G
	Composition	Each sugar coated tablet contains Sulbutiamine .....200 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 26164 dated 15-09-2022* Dy. No. dated 15-10-2010 *verified* Rs.8000/- dated 15-10-2010 *Photocopy* Rs.12000/- dated 18-03-2013 *Photocopy*
	Pharmacological Group	Aminopyrimidines And Derivatives
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arcalion by Servier France
	Me-too status	Arcalion by Servier France
	GMP status	Latest GMP validity: 27-07-2024
	Remarks of the Evaluator[3].	• Firm needs to submit evidence for conventional coating pan capable of conducting sugar coating process with Human machine interface (HMI) to control the opening and closing of the exhaust during coating time. • To explain procedure of sugar coating with details manufacturing for sealing , sub coating, smoothing, coloring & polishing with weigh gain in formulation before and after coating .
	Decision:Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
252.	**Name and address of manufacturer / Applicant**	**M/s Kanel Pharma (DML # 0000758)** **Plot No. 6 Street No. SS-3 RCCI National Industrial Estate Rawat.**
	Brand Name +Dosage Form + Strength	Tablet Hemofol
	Composition	Each Chewable tablet contains

		Iron III Hydroxide polymaltose complex equivalent to elemental Iron …….100 mg Folic Acid..... 0.35 mg
	Diary No. Date of R& I & fee	Dy. No. 7042 dated 02-07-2012 *(verified)* Rs.8000/- dated 02-07-2012 *(Original)* Rs.12000/- dated 21-01-2016 *(Original)*
	Pharmacological Group	Antianaemics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Ferrosoft fa by Hilton pharma
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Please submit details of manufacturing process keeping in view the flow, lubrication, disintegration, organoleptic properties, compressibility & compatibility. • Please define the hardness of chewable tablet.
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
253.	**Name and address of manufacturer / Applicant**	**M/s McOlson Research Laboratories (Pvt) Ltd. (DML # 0000664)** **26-Km Lahore Sharakpur Road District Sheikhupura.**
	Brand Name +Dosage Form + Strength	Tablet Koncept 20 mg
	Composition	Each enteric coated tablet contains Esomeprazole (as Magnesium Tri-hydrate) …… 20 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* Dy. No. 1420 dated 15-01-2011 Rs.8000/- dated 13-01-2011 *(photocopy)* Rs.12000/- dated 24-11-2014 *(photocopy)*
	Pharmacological Group	Antianaemics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Ferrosoft fa by Hilton pharma
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Please submit details of manufacturing process keeping in view the flow, lubrication, disintegration, organoleptic properties, compressibility & compatibility. • Please justify that why methyelene chloride has been part of your coating tablet while ICH guidelines categorically advise to avoid use of organic solvent in formulation. • Also provide evidence of methyelenechloride being part of any same formulation approved in countries with reference regulatory authorities declared by DRAP. • Please submit details of the testing parameters and its reference pharmacopeia / specifications .
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	

254.	**Name and address of manufacturer / Applicant**	**Applicant** **M/s Dyson Research Laboratories (Pvt) Ltd. (DML # 0000559)** **28-Km Ferozepur Road Lahore.** **Contract manufacturing from** **M/s Medisave Pharmaceuticals (DML # 0000681)** **Plot No.578-579 Sundar Industrial Estate Lahore.**
	Brand Name +Dosage Form + Strength	Onsetron Injection
	Composition	Each 4 ml solution contains Ondansetron (as 2HCl)..... 8 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 32983 dated 03-12-2021* Dy. No. 2442 dated 15-04-2013 Rs.50000/- dated 10-04-2013 *(Photocopy)*
	Pharmacological Group	Anti-emetic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	HPRA ie approved formulation
	Me-too status	Onset by Pharmedics
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision: Deferred for the submission of the following: • **Evidence of Section approval from Licensing Division.** • **Latest GMP inspection report conducted within last three years.** **Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.**	
255.	**Name and address of manufacturer / Applicant**	**M/s Life Pharmaceutical Company (DML # 0000194)** **24-III Industrial Estate Multan.**
	Brand Name +Dosage Form + Strength	Bebate Ointment 0.05 % w/w
	Composition	Each gram off ointment contains Betamethasone di-propionate … 0.05% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 21230 dated 28-07-2022* Dy. No. 5986 dated 23-05-2011 *(verified)* Rs.8000/- dated 23-05-2011 *(photocopy)* Rs.12000/- dated 12-21-2013 *(photocopy)*
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada approved formulation
	Me-too status	Provate by Don Valley
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision: Deferred for the submission of following: • **Evidence of Section approval from Licensing Division.** • **Latest GMP inspection report conducted within last three years.**	

	Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
256.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals Private Limited. (DML # 000333)** **14-km Adyala Road, Post Office Dahgal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Tablet Tepride XR
	Composition	Each extended released tablet contains Itopride HCl .....150 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 32410 dated 29-11-2021* Dy. No. 469 dated 03-11-2011 *(verified)* Rs.8000/- dated 28-10-2011 *(Photocopy)* Rs.12000/- dated 27-12-2012 *(photocopy)*
	Pharmacological Group	GREDs
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Ganaton OD by Abbott
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board. • Submit reference of specifications and testing method.
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
257.	**Name and address of manufacturer / Applicant**	**M/s Pharmedic Laboratories (Pvt) Ltd. (DML # 000228)** **16 Km Multan Road Lahore.**
	Brand Name +Dosage Form + Strength	Tranzine Injection 250 mg
	Composition	Each 5ml of solution in ampoules contains Tranexamic acid.....250 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 414 dated 06-02-2020* Dy. No. 848 dated 31-05-2011*(verified)* Rs.8000/- dated 31-05-2011 *(Photocopy)* Rs.12000/- dated 30-01-2020 *(Photocopy)*
	Pharmacological Group	Antihemorrhagics
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA JAPAN
	Me-too status	Zatrenex by zafa
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision: Deferred for the submission of following: • **Evidence of Section approval from Licensing Division.** • **Latest GMP inspection report conducted within last three years.** **Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.**	
258.	**Name and address of manufacturer / Applicant**	**M/s Pharmedic Laboratories (Pvt) Ltd. (DML # 000228)**

		16 Km Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Tablet Tranzine 500 mg
	Composition	Each film coated tablet contains Tranexamic acid.....500 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 165 dated 07-02-2020* Dy. No. 849 dated 31-05-2011-*verified* Rs.8000/- dated 31-05-2011-*photocopy* Rs.12000/- dated 30-01-2020-*original*
	Pharmacological Group	Antihemorrhagics
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Traumax by Siza Pharma
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision: Deferred for the submission of following: • **Evidence of Section approval from Licensing Division.** • **Latest GMP inspection report conducted within last three years.** **Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.**	
259.	**Name and address of manufacturer / Applicant**	**M/s Pharmedic Laboratories (Pvt) Ltd. (DML # 000228)** **16 Km Multan Road Lahore.**
	Brand Name +Dosage Form + Strength	Capsule Dozotine 60 mg
	Composition	Each enteric coated tablet contains Duloxetine (as HCl) .....60 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 156 dated 07-02-2020* Dy. No. 849 dated 31-05-2011 Rs.8000/- dated 31-05-2011-*photocopy* Rs.12000/- dated 30-01-2020-*original*
	Pharmacological Group	SNRIs
	Type of Form	Form 5
	Finished Product Specification	No reference provided
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verified
	Me-too status	Not verified
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit evidence of duloxetine in oral dosage form approved in Pakistan as well as RRAs countries. • Submit reference for finished product release specifications. • Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
260.	**Name and address of manufacturer / Applicant**	**M/s Cherished Pharmaceuticals (Pvt) Ltd. (DML # 000596) - Veterinary** **10-Km Sundar Raiwind Road Lahore.**
	Brand Name +Dosage Form + Strength	ADE Fast Injection ***(Veterinary)***

	Composition	Each ml contains Vitamin A..... 100,000 IU Vitamin D3…..... 40,000 IU Vitamin E .....40 mg
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 23705 dated 22-08-2022* Dy. No. 6115 dated 19-02-2018 Rs.20000/- *(Photocopy)*
	Pharmacological Group	Nutritional Supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specification
	Pack size & demanded price	--------
	Approval status of product in Reference Regulatory Authorities.	------
	Me-too status	ADE-MAX Injection by Nawan Labs (Reg # 58990)
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision: Deferred for the submission of following: • **Evidence of Section approval from Licensing Division.** • **Latest GMP inspection report conducted within last three years.** **Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.**	
261.	**Name and address of manufacturer / Applicant**	**M/s Zumars Pharma Fty (Pvt) Ltd.** **(DML # 000116)** **2-Industrial Area Malir Karachi.**
	Brand Name +Dosage Form + Strength	FLU-COUGH D syrup
	Composition	Each 5ml contains Diphenhydramine HCl .....13.5 mg Ammonium Chloride..... 50 mg Sodium Citrate..... 55 mg Menthol .....1 mg
	Diary No. Date of R& I & fee	*Dplicate Dossier (Dy. No. 23909)* Dated: 31-08-2021 Dy. No. 382 dated 28-05-2011 Rs. 8000/- dated 28-05-2011 Rs.20000/- dated 03-05-2016
	Pharmacological Group	Cough syrup
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	------
	Me-too status	Benadryl by Davis Pharma
	GMP status	Inspection report required
	Remarks of the Evaluator[3].	Inspection report required
	Decision: The Board decided to refer the case to sub committee for pharmaceuticals.	

Agenda of Evaluator PEC-IX

Case no. 01 Registration applications of newly granted DML

268.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Injection (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26294 dated 31.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 646535107796 dated 10.10.2023
	The proposed proprietary name / brand name	**GENTHATE 4.5M.I.U Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium (4.5MIU) eq to Colistin base activity 150mg
	Pharmacotherapeutic Group of (API)	Polymyxins ATC Code: J01XB01
	Pharmaceutical form of applied drug	Glass vial filled with white to off-white colored lyophilized powder.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLISTIMETHATE SODIUM EQ 150MG BASE/VIAL USFDA Approved.
	For generic drugs (me-too status)	CBA 150 Injection Reg. No. 103783 Imported by Biocare Pharma Lahore.
	Name and address of API manufacturer.	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. A1600307
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. A1680475, A1680476, A1680477
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **COlETIC 4.5MIU Inj Batch no. ____ exp. _____. manufactured by _____.** **Tests:** Description, identification, LOD, pH, uniformity of dosage, particulate matter, sterility, BET, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.		
API Lot No.	A1600307		
Description of Pack (Container closure system)	Power for solution for injection in Type- I glass vial.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	250 vials	250 vials	250 vials

Manufacturing Date	10.2022	10.22	10.22
Date of Initiation	04.10.2022	04.10.2022	04.10.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section, NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Verifiable from EudraGMP DUNS No. 305814345 & 401172630
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Colistimethate sodium (USP)** Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by AD I&E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Coletic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2.	3.2.P.8	Copy of executed BMRs of trial batches are required.
3.	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

269.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Injection (General)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26293 dated 31.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 41730109 dated 24.10.2023
	The proposed proprietary name / brand name	**GENTHATE 3M.I.U Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium (3MIU) eq to Colistin base activity 100mg
	Pharmacotherapeutic Group of (API)	Polymyxins ATC Code: J01XB01
	Pharmaceutical form of applied drug	Glass vial filled with white to off-white colored lyophilized powder.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colistimethate sodium 3 MIU, powder for solution for injection - (colistin methasulfonate sodium salt) - PL 34328/0016; UK/H/6255/003/DC MHRA Approved.
	For generic drugs (me-too status)	ColimeTHate Inj 3MIU Reg No. 108905 M/s Tabros Pharma Karachi.
	Name and address of API manufacturer.	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CMS2110006
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ±

		5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. CMS1707001, CMS1707002, CMS1707003,
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **COLETIC 3MIU Injection batch no. _____ exp._____. manufactured by _____.** Pictorial evidence is not submitted. **Tests:** Description, identification, LOD, pH, uniformity of dosage, particulate matter, free colistin, sterility, BET, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S. Denmark.		
API Lot No.	CMS 2110006		
Description of Pack (Container closure system)	Power for solution for injection in Type- I glass vial.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	250 vials	250 vials	250 vials
Manufacturing Date	10.2022	10.22	10.22
Date of Initiation	04.10.2022	04.10.2022	04.10.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section, NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Verifiable from EudraGMP DUNS No. 305814345 & 401172630

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Colistimethate sodium (USP)** Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by AD I&E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Coletic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

270.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Ointment Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25883 dated 26.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 861229598 dated 16.10.2023
	The proposed proprietary name / brand name	**TRIAMIGEN 0.1% Orabase Ointment**
	Strength / concentration of drug of Active	Each gram contains:

	Pharmaceutical ingredient (API) per unit	Triamcinolone acetonide.....1mg (0.1% w/w)
	Pharmacotherapeutic Group of (API)	Corticosteroids for local oral treatment ATC Code: A01AC01
	Pharmaceutical form of applied drug	Light yellow coloured semisolid emollient dental paste filled in printed aluminium tube.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10g, 15g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	KENALOG® IN ORABASE® (Triamcinolone Acetonide Dental Paste, USP), 0.1% USFDA Discontinued (Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons)
	For generic drugs (me-too status)	Kenalog in Orabase Ointment (Reg. No. 0094652) M/s GSK Pakistan.
	Name and address of API manufacturer.	M/s Farmabios S.p.A, Via Pavia 1-27027 Gropello Cairoli (PV) Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 2196NM4-0152221 analysed on 21.04.2023
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. B0011630, B0021630, B0031630, B0041524, B00161521, B0131621
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control,

		process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **KENALOG Orabase Ointment batch No. 5M3H exp. 05.2024. manufactured by M/s GSK Pakistan.** Pictorial evidence is not submitted. **Tests:** Description, identification, minimum fill, Uniformity of dosage and Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Farmabios S.p.A, Via Pavia 1-27027 Gropello Cairoli (PV) Italy.		
API Lot No.	2196NM0152221		
Description of Pack (Container closure system)	Light yellow coloured semisolid emollient dental paste filled in printed aluminium tube.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 tubes	500 tubes	500 tubes
Manufacturing Date	04.2023	04.2023	04.2023
Date of Initiation	24.04.2023	24.04.2023	24.04.2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted. 1 product
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Eudra GMP certificate No. IT-API-249/H/2022 valid till 01.10.2023 is submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Taken Loan from M/s Valor Pharma** **Triamcinolone Acetonide USP** Batch No.: 2196NM0152221 Mfg date: 01.08.2022 Exp date: 01.08.2027 Quantity: 150g Invoice No.: 474 Invoice date: 20.03.2023 Cleared by AD I&E DRAP Islamabad on 19.04.2023

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1	3.2.P.2.2	In manufacturing method given, it's not mentioned that at which step drug substance will be incorporated in the formulation. Provide clear detailed manufacturing method.	The firm vide letter No. Nil dated 25.11.2023 has submitted detailed manufacturing method. As per manufacturing method, polyethylene will be dissolved in mineral oil and then triamcinolone is added in this mixture.
2	3.2.P.2.2	Pictorial evidence of reference product (Kenalog) is required.	The pictorial evidence is submitted. Batch No. 5M3H
3	3.2.P.8	Copy of executed BMRs of trial batches are required.	Copies of BMR of batch Nos. T001, T002 & T003 are submitted.
4	-	The product applied has word "ointment" in its name. The RRA reference submitted is of oral paste (discontinued). Formulation adopted also does not indicate it to be a conventional ointment. The description of the product also mentions it as a dental paste. The monograph present in pharmacopoeia is also of a dental paste. Clarification regarding name of product is required and valid RRA reference is also required.	The firm has submitted that local brand leader's product name is orabase ointment. Formulation description applied is of emollient dental paste. The firm has submitted RRA evidence of "Oralone 0.1% dental paste", as per FDA database, the product is discontinued. No reason of discontinuation is mentioned. The product is approved in TGA Australia as "KENALOG IN ORABASE triamcinolone acetonide 1 mg/g paste tube" ARTG ID 19205

Decision: Approved. The registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 for change of name of product.

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

271.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section

	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Infusion Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25757 dated 25.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 36362201985 dated 20.10.2023
	The proposed proprietary name / brand name	**Gen-Zole 4mg/5ml Concentrate for solution for infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Zoledronic acid as monohydrate…..4mg
	Pharmacotherapeutic Group of (API)	Bisphosphonates ATC Code: M05BA08
	Pharmaceutical form of applied drug	Clear colourless solution filled in glass vial with flip-off seal.
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOMETA 4MG/5ML CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	For generic drugs (me-too status)	Zoledronic acid Normon 4mg/5ml Injection Reg No. 082059 M/s Merixil Pharma Islamabad (Importer).
	Name and address of API manufacturer.	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City ParawadaMandal, Vishakhapatnam, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 69020422 dated 13.03.2023

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. ZLA/FPR/001/18, ZLA/FPR/002/18, ZLA/FPR/003/18
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Macdronic 4mg/5ml Injection** **Tests:** Description, identification, particulate matter, pH, Assay, BET, Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City Parawada Mandal, Vishakhapatnam, Andhra Pradesh, India.		
API Lot No.	69020422		
Description of Pack (Container closure system)	Clear colourless solution filled in glass vial with flip-off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	03.2023	03.2023	03.2023
Date of Initiation	15.03.2023	15.03.2023	15.03.2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section, NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. E-1844451/DD/DCA/VSP/2022 dated 02.11.2022 valid till 01.11.2023, issued by Drug control administration Andhra Pradesh India.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	_____ Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by AD I&E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Macdronic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm vide letter No. nil dated 02.12.2023 has submitted pictorial evidence of the reference product macdronic 4mg/5ml injection, Batch No. 23004, mfg date: 05.2023 exp: 04.2025. Manufactured by M/s Macter International ltd.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Copies of BMR of batches T001, T002 and T003.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	The firm has submitted that drug substance is taken loan from M/s Medisave Pharma. Copy of clearance certificate and loan agreement is submitted. Batch No. 69010122 mfg 01.01.2022 exp: 31.12.2024. Invoice No. DP-378/2021-22 cleared by AD I&E DRAP Lahore on 18.03.2022
4	-	The product is a liquid vial (SVP), section approval is of infusion section. Justify.	Firm has submitted letter of issuance of DML vide No. 1-2/2019-Lic dated 14.02.2020, wherein Ampoule section SVP (General) is mentioned.

Decision: The Board Defered the case for evidence of aprovalof required manufacturing facility i.e., Liquid Injection Vial (SVP) section, from the Central Licensing Board.

272.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Infusion Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25884 dated 26.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 7397010517 dated 20.10.2023
	The proposed proprietary name / brand name	**Gen-Zole 5mg/100ml infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Zoledronic acid as monohydrate…..5mg
	Pharmacotherapeutic Group of (API)	Bisphosphonates ATC Code: M05BA08
	Pharmaceutical form of applied drug	Clear colourless solution filled in glass vial with flip-off seal.
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOLEDRONIC ACID 5MG/100ML SOLUTION FOR INFUSION MHRA Approved.
	For generic drugs (me-too status)	Zometa Infusion Reg No. 072551 M/s Novartis Pharma Karachi.
	Name and address of API manufacturer.	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City ParawadaMandal, Vishakhapatnam, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 69020422 dated 13.03.2023

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. ZLA/FPR/001/18, ZLA/FPR/002/18, ZLA/FPR/003/18
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Macdronic 5mg/100ml Infusion** **Tests:** Description, identification, particulate matter, pH, Assay, BET, Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City Parawada Mandal, Vishakhapatnam, Andhra Pradesh, India.		
API Lot No.	69020422		
Description of Pack (Container closure system)	Clear colourless solution filled in glass vial with flip-off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	03.2023	03.2023	03.2023
Date of Initiation	15.03.2023	15.03.2023	15.03.2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section.7
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. E-1844451/DD/DCA/VSP/2022 dated 02.11.2022 valid till 01.11.2023, issued by Drug control administration Andhra Pradesh India.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	_____ Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by AD I&E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Macdronic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm vide letter No. nil dated 02.12.2023 has submitted pictorial evidence of the reference product macdronic 5mg/100ml infusion, Batch No. 23003, mfg date: 11.2022 exp: 10.2024. Manufactured by M/s Macter International ltd.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Copies of BMR of batches T001, T002 and T003.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	The firm has submitted that drug substance is taken loan from M/s Medisave Pharma. Copy of clearance certificate and loan agreement is submitted. Batch No. 69010122 mfg 01.01.2022 exp: 31.12.2024. Invoice No. DP-378/2021-22 cleared by AD I&E DRAP Lahore on 18.03.2022
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.	The firm has stated that they will revise batch No. allotment system of trial batches to address this issue.

Decision: Approved.

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

273.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13942 dated 05.06.2023 RnI Verified. Dy. No 27659 dated 27.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 99142294489 dated 17.05.2023
	The proposed proprietary name / brand name	**CEFEGEN 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefepime hydrochloride eq to Cefepime…..... 500mg With L-Arginine.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporins ATC Code: J01DE01
	Pharmaceutical form of applied drug	White to pale yellow powder filled in glass vial with flip-off seal. Powder for solution for IM/ IV injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved.
	For generic drugs (me-too status)	Cefstar Injection 500mg Reg No. 076005 M/s Barrett and Hodgson.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CEIV/B2107059
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. CEIV/b1203011, CEIV/b1203012, CEIV/b1203013
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Maxipime 500mg Injection <u>Tests:</u>** Description, identification, particulate matter, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.		
API Lot No.	CEIV/B2107059		
Description of Pack (Container closure system)	White to pale yellow powder filled in glass vial with flip-off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	15.09.2022	15.09.2022	15.09.2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. NEW-WHO-GMP/CERT/KD/26116/2015/11/10947 dated 15.06.2015 valid till 14.04.2017, issued FDA Maharashtra India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	_____ Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by AD I&E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

274.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13943 dated 05.06.2023 RnI Verified. Dy. No 27660 dated 27.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 53358171 dated 16.05.2023
	The proposed proprietary name / brand name	**CEFEGEN 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefepime hydrochloride eq to Cefepime…..... 1gm With L-Arginine.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporins ATC Code: J01DE01
	Pharmaceutical form of applied drug	White to pale yellow powder filled in glass vial with flip-off seal. Powder for solution for IM/ IV injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved.
	For generic drugs (me-too status)	Cefstar Injection 1g Reg No. 076007 M/s Barrett and Hodgson.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CEIV/B2107059
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for

		36 months. Batch No. CEIV/b1203011, CEIV/b1203012, CEIV/b1203013
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Maxipime 1g Injection batch no._____exp. _____. manufactured by_____.** Pictorial evidence is not submitted. **Tests:** Description, identification, particulate matter, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.		
API Lot No.	CEIV/B2107059		
Description of Pack (Container closure system)	White to pale yellow powder filled in glass vial with flip-off seal.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	16.09.2022	16.09.2022	16.09.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. NEW-WHO-GMP/CERT/KD/26116/2015/11/10947 dated 15.06.2015 valid till 14.04.2017, issued FDA Maharashtra India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	_____ Batch No.: Mfg date: Exp date:

		Quantity: Invoice No.: Invoice date: Cleared by AD I&E
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

275.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23984 dated 02.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 8125522416 dated 12.09.2023
	The proposed proprietary name / brand name	**ARTEFOR 40mg/ml IM Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains; Artemether 40mg
	Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain ATC Code: P01BE02
	Pharmaceutical form of applied drug	Clear, colourless or almost colourless oily solution filled in glass ampoule.
	Reference to Finished product specifications	**Ph. Int Specifications.**
	Proposed Pack size	1's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified for 40mg strength.
	For generic drugs (me-too status)	Artem 40mg Injection Reg. No. 050689 M/s Hilton Pharma Karachi.
	Name and address of API manufacturer.	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. AM4N/20210919
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. AM2/20130710, AM2/20130711, AM2/20130712
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures,

		validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Artofer Inj. **Reference product:** Misomal Inj, Batch No. ____. mfg.: _____, Exp. _____ manufactured by M/s Pfizer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Content uniformity, clarity of solution, particulate matter, Assay, BET and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.		
API Lot No.	PGB03521AL		
Description of Pack (Container closure system)	Clear, colourless or almost colourless oily solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B#A004	B#A005	B#A006
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	26.12.2021	27.12.2021	28.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 25-KD/352 dated 15.12.2021 valid till 31.12.2025 issued by FDA Maharashtra is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Artemether** Batch No.: AM4N/20210919 Mfg date: 09.2021 Exp date: 08.2025 Quantity: 2kg Invoice No.: EXP/090018-21 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

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

Remarks of Evaluator:

Sr. No.	Section	Observation
1.		Valid and verifiable evidence of RRA approval of applied formulation is required.
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Misomal) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
3.	3.2.P.5.2	As per Ph. Int. monograph of the applied product, detector wavelength could be 216nm (Method A) or 254nm (Method B) for assay. The wavelength mentioned in submitted method of assay is 370nm. Justify.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

276.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17330 dated 11.06.2023
	Details of fee submitted	PKR 30,000/- Slip No. 5537894239 dated 16.06.2023
	The proposed proprietary name / brand name	**ARTEFOR 80mg/ml IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains; Artemether 80mg
	Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain ATC Code: P01BE02
	Pharmaceutical form of applied drug	Clear, colourless or almost colourless oily solution filled in glass ampoule.
	Reference to Finished product specifications	**Ph. Int Specifications.**

	Proposed Pack size	1's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product in WHO EML
	For generic drugs (me-too status)	Artem 80mg Injection Reg. No. 015529 M/s Hilton Pharma Karachi.
	Name and address of API manufacturer.	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. AM4N/20210919
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. AM2/20130710, AM2/20130711, AM2/20130712
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Artofer Inj. **Reference product:** Misomal Inj, Batch No. ____. mfg.: _____, Exp. _____ manufactured by M/s Pfizer Pakistan

		Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Content uniformity, clarity of solution, particulate matter, Assay, BET and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Calyx Chemicals and Pharmaceutical Limited, P-III and P-IV N-102/91/90 M.I.D.C. Tarapur Boisar Dist. Palghar Maharashtra India.		
API Lot No.	AM4N/20210919		
Description of Pack (Container closure system)	Clear, colourless or almost colourless oily solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B#A001	B#A002	B#A003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	26.12.2021	27.12.2021	28.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 25-KD/352 dated 15.12.2021 valid till 31.12.2025 issued by FDA Maharashtra is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Artemether** Batch No.: AM4N/20210919 Mfg date: 09.2021 Exp date: 08.2025 Quantity: 2kg Invoice No.: EXP/090018-21 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Misomal) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	
2.	3.2.P.5.2	As per Ph. Int. monograph of the applied product, detector wavelength could be 216nm (Method A) or 254nm (Method B) for assay. The wavelength mentioned in submitted method of assay is 370nm. Justify.	

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

277.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of tablet (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24325 dated 04.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 09288945 dated 15.09.2023
	The proposed proprietary name / brand name	**FORCIP 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ciprofloxacin hydrochloride eq. to Ciprofloxacin… 500mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones ATC Code: J01MA02
	Pharmaceutical form of applied drug	White to off-white, oblong scored on one side, biconvex, film coated tablet.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 100, 250, 500 and 750 mg Film-Coated Tablets (ciprofloxacin hydrochloride) - PL 36390/0142-0145 MHRA Approved
	For generic drugs (me-too status)	Ciproxin 500mg tablet Reg. No. 107222

		M/s Bayer Pakistan.
	Name and address of API manufacturer.	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. HB00U2107001
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. HA00N110913, HA00N110914, HA00N110915.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Forcip 500mg Tablet. **Reference product:** Ciproxin 500mg Tablet, Batch No._____. mfg.:_____, Exp. _____manufactured by M/s Bayer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Weight variation, DT, Uniformity of dosage unit, Dissolution, Assay. **CDP:**

		pH 1.2: F2 94.98 **pH 4.5:** F2 95.18 **pH 6.8:** F2 85.49
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.		
API Lot No.	HB00U2107001		
Description of Pack (Container closure system)	White to off-white, oblong scored on one side, biconvex, film coated tablet in alu-alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	05.12.2021	06.12.2021	07.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. ZJ20190157 dated 30.11.2019 valid till 29.11.2024 issued by National Medical products Administration China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ciprofloxacin HCl** Batch No.: HB00U2107001 Mfg date: 08.07.2021 Exp date: - Quantity: 10kg Invoice No.: KF2810210186 Invoice date: 28.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (ciproxin) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?
4.	3.2.P.8	Submit copy of executed BMRs of trial batches
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

278.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of tablet (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24326 dated 04.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 853539306 dated 15.09.2023
	The proposed proprietary name / brand name	**FORCIP 750mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ciprofloxacin hydrochloride eq. to Ciprofloxacin… 750mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones ATC Code: J01MA02

	Pharmaceutical form of applied drug	White to off-white, oblong scored on one side, biconvex, film coated tablet.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 100, 250, 500 and 750 mg Film-Coated Tablets (ciprofloxacin hydrochloride) - PL 36390/0142-0145 MHRA Approved
	For generic drugs (me-too status)	Cipesta 750mg tablet Reg. No. 055949 M/s Getz Pharma Karachi.
	Name and address of API manufacturer.	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. HB00U2107001
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. HA00N110913, HA00N110914, HA00N110915.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch

		analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Forcip 750mg Tablet. **Reference product:** Hiflox 750 Tablet, Batch No._____. mfg.:_____, Exp. _____ manufactured by M/s Bayer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Weight variation, DT, Uniformity of dosage unit, Dissolution, Assay. **CDP:** **pH 1.2:** F2 98.61 **pH 4.5:** F2 97.71 **pH 6.8:** F2 97.81
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.		
API Lot No.	HB00U2107001		
Description of Pack (Container closure system)	White to off-white, oblong scored on one side, biconvex, film coated tablet in alu-alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	05.12.2021	06.12.2021	07.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. ZJ20190157 dated 30.11.2019 valid till 29.11.2024 issued by National Medical products Administration China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ciprofloxacin HCl** Batch No.: HB00U2107001 Mfg date: 08.07.2021 Exp date: - Quantity: 10kg Invoice No.: KF2810210186 Invoice date: 28.10.2021

		Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Hiflox) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?
4.	3.2.P.8	Submit copy of executed BMRs of trial batches
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

279.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of tablet (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24324 dated 04.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 1968847012 dated 12.09.2023
	The proposed proprietary name / brand name	**FORCIP 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ciprofloxacin hydrochloride eq. to Ciprofloxacin… 250mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones ATC Code: J01MA02
	Pharmaceutical form of applied drug	White to off-white, oblong scored on one side, biconvex, film coated tablet.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 100, 250, 500 and 750 mg Film-Coated Tablets (ciprofloxacin hydrochloride) - PL 36390/0142-0145 MHRA Approved
	For generic drugs (me-too status)	Ciproxin 500mg tablet Reg. No. 107222 M/s Bayer Pakistan.
	Name and address of API manufacturer.	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. HB00U2107001
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at

		40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. HA00N110913, HA00N110914, HA00N110915.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Forcip 250mg Tablet. **Reference product:** Ciproxin 250mg Tablet, Batch No._____. mfg.:_____, Exp. _____manufactured by M/s Bayer Pakistan Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Weight variation, DT, Uniformity of dosage unit, Dissolution, Assay. **CDP:** **pH 1.2:** F2 94.98 **pH 4.5:** F2 95.18 **pH 6.8:** F2 85.49
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Langhua Pharmaceutical Co. Ltd., No. 7, Donghai 3rd Avenue, Zhejiang provincial chemical and medical materials base Linhai Zone, Linhai City, Zhejiang Province, China.		
API Lot No.	HB00U2107001		
Description of Pack (Container closure system)	White to off-white, oblong scored on one side, biconvex, film coated tablet in alu-alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	05.12.2021	06.12.2021	07.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. ZJ20190157 dated 30.11.2019 valid till 29.11.2024 issued by National Medical products Administration China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ciprofloxacin HCl** Batch No.: HB00U2107001 Mfg date: 08.07.2021 Exp date: - Quantity: 10kg Invoice No.: KF2810210186 Invoice date: 28.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (ciproxin) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.5.2	In dissolution, wavelength for analysis is mentioned as 282nm, USP monograph mentions that it should be 276nm. Justify this difference.
3.	3.2.P.5.3	In system suitability, it is mentioned that it was performed using replicate injections (n=6). As per USP monograph it should be done by ensuring resolution of NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, System suitability solution. Why system suitability is not done as per USP monograph?
4.	3.2.P.8	Submit copy of executed BMRs of trial batches
5.	3.2.P.8	The chromatogram of system suitability done as per USP monograph is required. Further in every chromatogram there is a minor unidentified peak at RT 4.2. There is no chromatogram of blank/ mobile phase injection either for comparison. Justify.
6.	-	Why batch numbers of all trial batches of different strength are similar, batch numbering should be unique for each batch.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

280.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No.

		K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection Ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17328 dated 11.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 030692819420 dated 04.07.2023
	The proposed proprietary name / brand name	**CITIFOR 250mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Citicoline sodium eq to Citicoline…… 250mg
	Pharmacotherapeutic Group of (API)	Other psychostimulants and nootropics ATC Code: N06BX06
	Pharmaceutical form of applied drug	Clear colourless or almost colourless solution filled in glass ampoule.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified. The reference of ANSM France given stands repealed.
	For generic drugs (me-too status)	Sauran 250mg Injection Reg. No. 030297 M/s Siza International Lahore.
	Name and address of API manufacturer.	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CTS-00891020
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. CTS-00010215, CTS-00020215, CTS-00030315.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Citifor Inj. **Reference product:** Neuroline Inj, Batch No. ___. mfg.: ____, Exp. manufactured by M/s _____ Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Volume variation, pH, Clarity of solution, particulate matter in Injection, Assay, BET & Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India		
API Lot No.	CTS-00891020		
Description of Pack (Container closure system)	Clear colourless or almost colourless solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C001	C002	C003
Batch Size	1000 ampoules	1000	1000 ampoules

		ampoules	
Manufacturing Date	01.2022	01.2022	01.2022
Date of Initiation	16.01.2022	16.01.2022	16.01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 20021883 dated 03.03.2021 valid till 02.03.2024 issued by Food and drug control administration Gujrat state India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Citicoline Sodium** Batch No.: CTS-00891020 Mfg date: 10.2020 Exp date: 09.2024 Quantity: 7kg Invoice No.: EXP/180522(20-21) Invoice date: 18.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	The reference of ANSM France given is repealed. Provide valid reference of RRA approval.
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neuroline) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
3.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

281.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection Ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17329 dated 11.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 428167228907 dated 04.07.2023
	The proposed proprietary name / brand name	**CITIFOR 1g/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Citicoline sodium eq to Citicoline……. 1g
	Pharmacotherapeutic Group of (API)	Other psychostimulants and nootropics ATC Code: N06BX06
	Pharmaceutical form of applied drug	Clear colourless or almost colourless solution filled in glass ampoule.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified. The reference of ANSM France given stands repealed.
	For generic drugs (me-too status)	Sauran 1g Injection Reg. No. 030296 M/s Siza International Lahore.
	Name and address of API manufacturer.	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		Batch No. CTS-00891020
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. CTS-00010215, CTS-00020215, CTS-00030315.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Citifor Inj. **Reference product:** Neuroline Inj, Batch No. ___. mfg.: ___, Exp. manufactured by M/s _____ Pictorial evidence not submitted. **Tests done:** Appearance, Identification, Volume variation, pH, Clarity of solution, particulate matter in Injection, Assay, BET & Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Bajaj Healthcare Ltd. (Unit-IV), 1717/1718, GIDC Panoli Tal-Ankleshwar Dist. Bharuch Gujrat India		
API Lot No.	CTS-00891020		
Description of Pack (Container closure system)	Clear colourless or almost colourless solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C004	C005	C006
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	01.2022	01.2022	01.2022
Date of Initiation	16.01.2022	16.01.2022	16.01.2022
No. of Batches	3		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 20021883 dated 03.03.2021 valid till 02.03.2024 issued by Food and drug control administration Gujrat state India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Citicoline Sodium** Batch No.: CTS-00891020 Mfg date: 10.2020 Exp date: 09.2024 Quantity: 7kg Invoice No.: EXP/180522(20-21) Invoice date: 18.10.2021 Cleared by: AD I&E DRAP Karachi on 18.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	The reference of ANSM France given is repealed. Provide valid reference of RRA approval.
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neuroline) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
3.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

282.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Tablet section (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 18306 dated 20.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 08287098124 dated 09.07.2023
	The proposed proprietary name / brand name	**DESLO 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Desloratadine……5mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use ATC Code: R06AX27
	Pharmaceutical form of applied drug	Film coated light yellow colour biconvex round tablet in Alu-Alu blister with leaflet pack in unit carton.
	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	DESLORATADINE 5 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Alenor 5mg Tablet Reg. No. 053481 M/s Macter International Karachi.
	Name and address of API manufacturer.	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. DSL/002/21
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months.

		The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. DH-1501, DH-1502, DH-1503.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Deslo. **Reference product:** Neo-Antial, Batch No. 003H ___. mfg.: ___, Exp. manufactured by M/s Sami Pictorial evidence not submitted. **Tests done:** Description, dissolution, DT, Average weight, Uniformity of dosage unit & Assay. **CDP:** **pH 1.2:** F2 dissolution above 85% in 15min **pH 4.5:** F2 dissolution above 85% in 15min **pH 6.8:** F2 51%
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.		
API Lot No.	DSL/002/21		
Description of Pack (Container closure system)	Film coated light yellow colour biconvex round tablet in Alu-Alu blister with leaflet pack in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DS-001	DS-002	DS-003
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	01.2022	01.2022	01.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. HFW-H (Drugs) 93/91 dated 05.01.2023 valid till 11.05.2024

		issued by Health and welfare department Himachal Pradesh state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Desloratadine** Batch No.: DSL/002/21 Mfg date: 10.2021 Exp date: 09.2024 Quantity: 0.25kg Invoice No.: EXP/090018 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi on 22.11.21
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Neo-Antial) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required
2.	3.2.P.2	In graphs of CDP, products Lewdes and Clarinex are compared. These products are related to other manufacturers, why are these mentioned here, justify.
3.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

283.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Oral Liquid (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 23985 dated 02.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 889855969206 dated 12.09.2023
	The proposed proprietary name / brand name	**DESFORA SYRUP 0.5mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains; Desloratadine… 0.5mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use ATC Code: R06AX27
	Pharmaceutical form of applied drug	A clear colourless syrup with bubble gum flavour
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Desloratadine 0.5 mg/ml oral solution - PL 17907/0502; UK/H/5946/001/DC MHRA Approved.
	For generic drugs (me-too status)	Desora Syrup Reg. No. 055192 M/s SJ&G Fazul Ellahi Karachi.
	Name and address of API manufacturer.	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. DSL/002/21
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. DH-1501, DH-1502, DH-1503.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture,

		manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Desfora. **Reference product:** Neo-Antial syrup, Batch No. 2518 mfg.: 02.2019, Exp. 01.2021 manufactured by M/s Sami Pictorial evidence not submitted. **Tests done:** Description, identification, filled volume, deliverable volume, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Meropen Laboratories Ltd. Village Masulkhana Parwanoo Distt, Solan India.		
API Lot No.	DSL/002/21		
Description of Pack (Container closure system)	A clear colourless syrup with bubble gum flavour		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	D-001	D-002	D-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	07.12.2021	08.12.2021	09.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. HFW-H (Drugs) 93/91 dated 05.01.2023 valid till 11.05.2024 issued by Health and welfare department Himachal Pradesh state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Desloratadine** Batch No.: DSL/002/21 Mfg date: 10.2021 Exp date: 09.2024 Quantity: 0.25kg Invoice No.: EXP/090018 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi on 22.11.21

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

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2	Pictorial evidence of reference product used in pharmaceutical equivalence is required.
2.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

284.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi (DML No. 000924)**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, SITE (SHW) Phase-II Karachi. DML No. 000924
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Sterile liquid injection Ampoule SVP (general) section vide letter No. 2-3/2016-Lic dated 14.06.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27248 dated 20.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 6080374876 dated 12.08.2022
	The proposed proprietary name / brand name	**NALFORT 10mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains; Nalbuphine hydrochloride……. 10mg
	Pharmacotherapeutic Group of (API)	Morphinan derivatives ATC Code: N02AF02
	Pharmaceutical form of applied drug	1ml glass ampoule, containing solution for injection.
	Reference to Finished product specifications	**Innovator Specifications.**

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified. The reference of USFDA is discontinued.
	For generic drugs (me-too status)	Kinz 10mg injection Reg. No. 018686 M/s Sami pharmaceuticals Karachi.
	Name and address of API manufacturer.	M/s Micro Orgo-Chem Shed No. C-1/B, LIC Sector GIDC, VAPI, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. MO/NBP/2101
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. MO/NBP/1401, MO/NBP/1402, MO/NBP/1403.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Nalfort 10mg Injection, Batch No. NF-001. **Reference product:** Nubain Injection, Batch No. NL2245. Exp. 12.2023

		manufactured by M/s Endo Pharmaceuticals. Pictorial evidence is submitted. **Tests done:** Appearance, Identification, Volume variation, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Micro Orgo-Chem Shed No. C-1/B, LIC Sector GIDC, VAPI, Gujrat India		
API Lot No.	MO/NBP/2101		
Description of Pack (Container closure system)	Clear colourless or almost colourless solution filled in glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NF-001	NF-002	-
Batch Size	2000 ampoules	2000 ampoules	-
Manufacturing Date	05.2022	05.2022	-
Date of Initiation	05.2022	05.2022	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. S-GMP & GLP/21092920 valid till 14.09.2023 issued by Food and drug control administration Gujrat state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Nalbuphine Hydrochloride** Batch No.: MO/NBP/2101 Mfg date: 03.2021 Exp date: 01.2024 Quantity: 0.25kg Invoice No.: EX/RU/031/21-22 Invoice date: 25.10.2021 Cleared by: AD I&E DRAP Karachi on 22.11.2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	The product mentioned on fee slip is Relief injection 10mg/ml, applied product is NALFORT 10mg/ml injection. Clarify.
2.	-	The reference of USFDA given is discontinued. Provide valid reference of RRA approval.
3.	3.2.P.2.2	Origin of reference product in pharmaceutical equivalence (Nubain injection) is not clearly mentioned. Further the pictorial evidence does not indicate the batch No.
4.	3.2.P.8	The fill volume applied is 1ml, in stability studies the size of ampoules mentioned is 5ml. Clarify.
5.	3.2.P.8	Submit copy of executed BMRs of trial batches

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

285.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Himark Laboratories (Pvt.) ltd. Plot No. 37-A, Sundar Industrial Estate Lahore. (DML No. 000909)**
	Name, address of Manufacturing site.	M/s Himark Laboratories (Pvt.) ltd. Plot No. 37-A, Sundar Industrial Estate Lahore. DML No. 000909
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 38/2023-DRAP(AD-27101426183-965) dated 06.04.2023 valid till 27.03.2025 issued by DRAP Lahore is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-67/2005-Lic dated 26.09.2019 is submitted. Sachet (General) Section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25281 dated 17.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 6814858060 dated 02.10.2023
	The proposed proprietary name / brand name	**OMIRIN Insta 20mg/1680mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains; Omeprazole…..... 20mg Sodium bicarbonate 1680mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	Pharmaceutical form of applied drug	Powder in unit pack sachet for oral suspension.
	Reference to Finished product specifications	**Innovator Specifications.**

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zegerid OTC 20mg Sachet USFDA Approved.
	For generic drugs (me-too status)	Risek Insta sachet 20mg Reg. No. 070851 M/s Getz Pharma Karachi.
	Name and address of API manufacturer.	**Omeprazole** M/s Tagoor Laboratories Pvt. Ltd. Unit-1, Sy. No. 29 Tupakulagudem, Pochvaram Panchayat, Tallpudi Mandal, East Godavari, Andhra Pradesh India. **Sodium Bicarbonate** M/s Emmennar Pharma Provate Limited, Plot No. A-4, Industrial Estate, Sanath Nagar, Hyderabad Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. OPZ-I/00103/22 SBC-20020
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (60 months for sodium bicarbonate) OPZ-0010619, OPZ-0020619, OPZ-0030619. SBC-1703002, SBC-1703003, SBC-1703004.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Omirin 20/1680 Sachet Batch No. **Reference product:** Risek isnta 20mg Sachet, Batch No._____. mfg.:_____, Exp. _____manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics before and after reconstitution, Identification, General tests for sodium, pH, Loss on Drying, Uniformity of dosage units, dissolution test, Assay. **CDP:** Not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Omeprazole** M/s Tagoor Laboratories Pvt. Ltd. Unit-1, Sy. No. 29 Tupakulagudem, Pochvaram Panchayat, TallpudiMandal, East Godavari, Andhra Pradesh India. **Sodium Bicarbonate** M/s Emmennar Pharma Provate Limited, Plot No. A-4, Industrial Estate, Sanath Nagar, Hyderabad Telangana India.		
API Lot No.	OPZ-I/00103/22 SBC-20020		
Description of Pack (Container closure system)	White to off white powder in aluminium foil sachet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 sachet	100 sachet	100 sachet
Manufacturing Date	12.2022	12.2022	12.2022
Date of Initiation	19.12.2022	19.12.2022	19.12.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. DCD/SPL-1/CR-1733/2021-22 dated 31.01.2022 valid till 30.01.2023 issued by Drug Control department Karnataka state India is submitted.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Omperazole** Batch No. OPZ-1/00103/22 Mfg: 03.2022 Exp: 08.2024 Invoice No.: EXP/102 (22-23) Dated: 29.07.2022 Cleared by: **Sodium Bicarbonate** Batch No. SBC-20020 Mfg: 09.2020 Exp: 08.2025 Invoice No.: SD/22-23/0022 Dated: 05.08.2022 Cleared by:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2	In pharmaceutical equivalence, batch No. mfg date and exp date of reference product (risek) is required. Pictorial evidence of reference product is also required. CDP is not performed, justify.	The firm vide letter No. nil dated 13.12.2023 has submitted pictorial evidence of reference product. Details are given below; Risek Insta 20mg Sachet. Batch No. 219D16. Mfg 10.21, Exp 10.23 CDP has also been performed at 3 physiological pH. The results of both test and reference product are comparable.
2.	-	Submitted copies of AD attested invoices of both drug substances or their clearance certificates issued by DRAP.	The firm has submitted NOC for import of Raw material dated 26.12.2019 issued by AD I&E DRAP Lahore. The material was cleared by DHL and delivered directly to the Firm. The firm has submitted copies DHL bill receipts.
3.	-	Copy of GMP certificate of drug product manufacturer is required for both drug substances.	Submitted. Cetificate No. HM07-15030/45/2023-DD-DDCA dated 15.05.2023. Valid till 14.05.2024. Issued by Drug Control Administration Andhra Pradesh India.

Decision: Approved.

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

286.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Himark Laboratories (Pvt.) ltd. Plot No. 37-A, Sundar Industrial Estate Lahore. (DML No. 000909)**

	Name, address of Manufacturing site.	M/s Himark Laboratories (Pvt.) ltd. Plot No. 37-A, Sundar Industrial Estate Lahore. DML No. 000909
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 38/2023-DRAP(AD-27101426183-965) dated 06.04.2023 valid till 27.03.2025 issued by DRAP Lahore is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-67/2005-Lic dated 26.09.2019 is submitted. Sachet (General) Section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25282 dated 17.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 83217485702 dated 02.10.2023
	The proposed proprietary name / brand name	**OMIRIN Insta 40mg/1680mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains contains; Omeprazole…..... 40mg Sodium bicarbonate 1680mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC Code: A02BC01
	Pharmaceutical form of applied drug	Powder in unit pack sachet for oral suspension.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	1x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zegerid OTC 40mg Sachet USFDA Approved.
	For generic drugs (me-too status)	Risek Insta sachet 40mg Reg. No. 058548 M/s Getz Pharma Karachi.
	Name and address of API manufacturer.	**Omeprazole** M/s Tagoor Laboratories Pvt. Ltd. Unit-1, Sy. No. 29 Tupakulagudem, Pochvaram Panchayat, Tallpudi Mandal, East Godavari, Andhra Pradesh India. **Sodium Bicarbonate** M/s Emmennar Pharma Provate Limited, Plot No. A-4, Industrial Estate, Sanath Nagar, Hyderabad Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. OPZ-I/00103/22 SBC-20020
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (60 months for sodium bicarbonate) OPZ-0010619, OPZ-0020619, OPZ-0030619. SBC-1703002, SBC-1703003, SBC-1703004.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Omirin 40/1680 Sachet Batch No. **Reference product:** Risek isnta 40mg Sachet, Batch No._____. mfg.:_____, Exp. _____manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics before and after reconstitution, Identification, General tests for sodium, pH, Loss on Drying, Uniformity of dosage units, dissolution test, Assay. **CDP:** Not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	**Omeprazole** M/s Tagoor Laboratories Pvt. Ltd. Unit-1, Sy. No. 29 Tupakulagudem, Pochvaram Panchayat, TallpudiMandal, East Godavari, Andhra Pradesh India. **Sodium Bicarbonate** M/s Emmennar Pharma Provate Limited, Plot No. A-4, Industrial Estate, Sanath Nagar, Hyderabad Telangana India.		
API Lot No.	OPZ-I/00103/22 SBC-20020		
Description of Pack (Container closure system)	White to off white powder in aluminium foil sachet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 sachet	100 sachet	100 sachet
Manufacturing Date	12.2022	12.2022	12.2022
Date of Initiation	19.12.2022	19.12.2022	19.12.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole** . **Sodium Bicarbonate** .
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Omperazole** Batch No. OPZ-1/00103/22 Mfg: 03.2022 Exp: 08.2024 Invoice No.: EXP/102 (22-23) Dated: 29.07.2022 Cleared by:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2	In pharmaceutical equivalence, batch No. mfg date and exp date of reference product (risek) is required.	The firm vide letter No. nil dated 13.12.2023 has submitted pictorial

		Pictorial evidence of reference product is also required. CDP is not performed, justify.	evidence of reference product Risek insta 40mg along with details. CDP has also been performed at 3 physiological pH. The results of both test and reference product are comparable.
2.	3.2.P.8	Batch numbers of different strengths should not be identical. Batch numbers need to be unique.	The firm has stated that they have revised their batch number system and in future all batch numbers will be unique.
3.	-	Submitted copies of AD attested invoices of both drug substances or their clearance certificates issued by DRAP.	The firm has submitted NOC for import of Raw material dated 26.12.2019 issued by AD I&E DRAP Lahore. The material was cleared by DHL and delivered directly to the Firm. The firm has submitted copies DHL bill receipts.
4.	-	Copy of GMP certificate of drug product manufacturer is required for both drug substances.	Submitted. Cetificate No. HM07-15030/45/2023-DD-DDCA dated 15.05.2023. Valid till 14.05.2024. Issued by Drug Control Administration Andhra Pradesh India.

Decision: Approved.

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

287.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Himark Laboratories (Pvt.) ltd. Plot No. 37-A, Sundar Industrial Estate Lahore. (DML No. 000909)**
	Name, address of Manufacturing site.	M/s Himark Laboratories (Pvt.) ltd. Plot No. 37-A, Sundar Industrial Estate Lahore. DML No. 000909
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 38/2023-DRAP(AD-27101426183-965) dated 06.04.2023 valid till 27.03.2025 issued by DRAP Lahore is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 1-67/2005-Lic dated 26.09.2019 is submitted. Oral liquid Syrup Section approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25278 dated 17.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 38977458596 dated 02.10.2023
	The proposed proprietary name / brand name	**SETRON 4mg/5ml Syrup**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Ondansetron hydrochloride dihydrate eq. to Ondansetron……4mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	Pharmaceutical form of applied drug	Oral syrup in amber coloured glass bottle.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	30ml and 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ONDANSETRON 4MG/5ML SYRUP MHRA Approved.
	For generic drugs (me-too status)	Onsetron 4mg/5ml Reg. No. 109747 M/s Dyson Research Laboratories Lahore.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50, C62 & C-63 KSSIDC Industrial Estate, Doddaballapur, Bengaluru India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. AOND-22005
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. 17002, 17003, 17004.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch

		analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Setron 4mg/5ml Syrup **Reference product:** Onseron 4mg/5ml syrup, Batch No._____. mfg.:_____, Exp. _____manufactured by M/s Indus Pharma Pictorial evidence is not submitted. **Tests done:** Description, Identification, Colour, Deliverable volume, pH, Microbial testing & Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50, C62 & C-63 KSSIDC Industrial Estate, Doddaballapur, Bengaluru India..		
API Lot No.	AOND-22005		
Description of Pack (Container closure system)	Amber color glass bottle with aluminium cap, packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	12.2022	12.2022	12.2022
Date of Initiation	6.12.2022	6.12.2022	6.12.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. DCD/SPL-1/CR-1733/2021-22 dated 31.01.2022 valid till 30.01.2023 issued by Drug Control department Karnataka state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ondansetron HCl dihydrate** Batch No. AOND-22005 Mfg: 07.2021 Exp: 06.2026 Invoice No.: EXP/22-23/1000722 Dated: 13.11.2022 Cleared by:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2	In pharmaceutical equivalence, batch No. mfg date and exp date of reference product (Onseron) is required. Pictorial evidence of reference product is also required.	The firm vide letter No. nil dated 13.12.2023 has submitted pictorial evidence of reference product Risek insta 40mg along with details.
2.	3.2.P.8	Batch numbers of different products should not be identical. Batch numbers need to be unique.	The firm has stated that they have revised their batch number system and in future all batch numbers will be unique.
3.	-	Submitted copies of AD attested invoices of both drug substances or their clearance certificates issued by DRAP.	The firm has submitted NOC for import of Raw material dated 26.12.2019 issued by AD I&E DRAP Lahore. The material was cleared by DHL and delivered directly to the Firm. The firm has submitted copies DHL bill receipts.

Decision: Approved.

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

288.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt.) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera (DML No. 000946)**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt.) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera DML No. 000946
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Liquid Infusion-LVP (General) section vide letter No. 3-8/2017-Lic dated 11.11.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22820 dated 18.09.2023

	Details of fee submitted	PKR 30,000/- Slip No. 7568161557 dated 13.09.2023
	The proposed proprietary name / brand name	**JHK-Sol Peads 500ml IV Infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains; Dextrose anhydrous .....4.30g Sodium chloride..... 0.18g
	Pharmacotherapeutic Group of (API)	electrolytes with carbohydrates ATC Code: B05BB02
	Pharmaceutical form of applied drug	Clear sterile solution for infusion packed in 500ml LDPE plastic bottles **with euro cap**.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SODIUM CHLORIDE 0.18% AND GLUCOSE 4% INTRAVENOUS INFUSION MHRA Approved.
	For generic drugs (me-too status)	Unisol-Peads IV Infusion Reg. No. 078597 M/s Unisa Pharmaceutical Industries Nowshera
	Name and address of API manufacturer.	**Dextrose;** M/s Xiwang Pharmaceutical Co. Ltd. Zouping County Xiwang Industrial Park, Binzhou City Shandong China. **Sodium Chloride;** M/s Dominion Salt Limited, 89 Totara Street Mount Maunganui, New Zealand.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Dextrose;** (Not submitted) **Sodium Chloride;** (Not Submitted)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated

		as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (S-Part not submitted) **Dextrose;** **Sodium Chloride;** As per minutes of 323rd RB, "Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 24 months."
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** J-Sol Peads Infusion. **Reference product:** **Unisol-Peads**, Pictorial evidence not submitted. **Tests done:** Description, Identification, pH, 5-Hydroxymethylfurfural and related substances, Assay, BET
	Analytical method validation/verification of product	(Not submitted)

STABILITY STUDY DATA

Manufacturer of API	**Dextrose;** M/s Xiwang Pharmaceutical Co. Ltd. Zouping County Xiwang Industrial Park, Binzhou City Shandong China. **Sodium Chloride;** M/s Dominion Salt Limited, 89 Totara Street Mount Maunganui, New Zealand.		
API Lot No.	**Dextrose;** 202106156 **Sodium Chloride;**		
Description of Pack (Container closure system)	Clear sterile solution for infusion packed in 500ml LDPE plastic bottles **with euro cap**.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 1	Trial 2	Trial 3
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	04.2022	04.2022	04.2022

Date of Initiation		21.04.2022	21.04.2022	21.04.2022
No. of Batches		3		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dextrose;** Copy of certificate No. SD20170644 dated 12.01.2018 valid till 11.01.2023 issued by National Medical Product Administration is submitted. **Sodium Chloride;** Copy of certificate No. TT60-565-16-3 dated 28.07.2021 valid till 28.01.2023 issued by MEDSAFE New Zealand is submitted.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dextrose anhydrous;** Taken loan from M/s Atlantic Pharmaceutical Laboratories Peshawar. Batch No.: 202106156 Quantity: 48000Kg Invoice No.: KF2105111A Invoice date: 23.06.2021 Cleared by: AD I&E DRAP Peshawar **Sodium Chloride;** Taken loan from M/s Atlantic Pharmaceutical Laboratories Peshawar. Batch No. Mfg date: Exp date: Quantity: 24 metric tons Invoice No.: Invoice date: Cleared by:		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S	The S part in Module 3 is not provided. It is required for both drug substances.	The firm vide letter No. nil dated nil has submitted that *"S part has already been submitted and approved in 323rd meeting of Registration Board for JHK-Sol DS 500ml & 100ml, JHK Sol-NS, JHK-Sol 5% & 10%. However copy of DMF has been enclosed for kind reference"*

			The firm has only submitted a single page reply. No DMF is submitted with the letter	
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Unisol-Peads) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm vide letter No. nil dated nil has submitted following details along with pictorial evidence; Unisol peads, Batch No. 2081076 Mfg date 08.2022, EXP 07.2024 Manifacturer: Unisa Pharma.	
3.	3.2.P.5.3	Verification of analytical procedures is not submitted.	The firm has submitted that they have already submitted it dossiers of JHK Sol DS 500ml & 1000ml and is attached for reference. The reply is a single page only, the firm has not submitted the verification studies of analytical procedures.	
4.	3.2.P.8	Submit studies conducted for potential water loss from your primary container (semipermeable LDPE container) as per ICH guidelines [ICH Q1A(R2)].	The firm has stated that for test of water loss, fill volume test has been relied upon since applied product has same solutes as already approved for JHK-SOL-DS	
5.	3.2.P.8	Submitted copies of executed BMRs of trial batches.	Submitted.	
6.	3.2.P.8	The copy of invoice of Sodium chloride is not readable. Its clear copy is required.	Submitted.	

Decision: The board deliberated on the matter and keeping in view the fact that products of the firm have already been approved in 323rd meeting of RB on basis of data submitted in S part of the dossier, the Board approved the application of "JHK-Sol Peads 500ml IV Infusion.".

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

289.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt.) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera (DML No. 000946)**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt.) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera DML No. 000946
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of Liquid Infusion-LVP (General) section vide letter No. 3-8/2017-Lic dated 11.11.2021 is submitted.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22819 dated 18.09.2023
	Details of fee submitted	PKR 30,000/- Slip No. 7823151814 dated 13.09.2023
	The proposed proprietary name / brand name	**JHK-Sol DS$^{1/2}$ 500ml IV Infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains; Dextrose anhydrous…….5g Sodium chloride..... 0.45g
	Pharmacotherapeutic Group of (API)	electrolytes with carbohydrates ATC Code: B05BB02
	Pharmaceutical form of applied drug	Clear sterile solution for infusion packed in 500ml LDPE plastic bottles **with euro cap**.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER USFDA Approved.
	For generic drugs (me-too status)	Unisol-DS1/2 IV Infusion Reg. No. 075544 M/s Unisa Pharmaceutical Industries Nowshera
	Name and address of API manufacturer.	**Dextrose;** M/s Xiwang Pharmaceutical Co. Ltd. Zouping County Xiwang Industrial Park, Binzhou City Shandong China. **Sodium Chloride;** M/s Dominion Salt Limited, 89 Totara Street Mount Maunganui, New Zealand.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		Dextrose; (Not submitted) **Sodium Chloride;** (Not Submitted)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (S-Part not submitted) **Dextrose;** **Sodium Chloride;** As per minutes of 323rd RB, "Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 24 months."
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** J-Sol DS1/2 Infusion. **Reference product: Unisol-DS1/2 Infusion**, Pictorial evidence not submitted. **Tests done:** Description, Identification, pH, 5-Hydroxymethylfurfural and related substances, Assay, BET
	Analytical method validation/verification of product	(Not submitted)

STABILITY STUDY DATA	
Manufacturer of API	**Dextrose;** M/s Xiwang Pharmaceutical Co. Ltd. Zouping County Xiwang Industrial Park, Binzhou City Shandong China. **Sodium Chloride;** M/s Dominion Salt Limited, 89 Totara Street Mount Maunganui, New Zealand.
API Lot No.	**Dextrose;** 202106156 **Sodium Chloride;**
Description of Pack (Container closure system)	Clear sterile solution for infusion packed in 500ml LDPE plastic bottles **with euro cap**.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

		Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		Trial 1	Trial 2	Trial 3
Batch Size		500 bottles	500 bottles	500 bottles
Manufacturing Date		04.2022	04.2022	04.2022
Date of Initiation		21.04.2022	21.04.2022	21.04.2022
No. of Batches		3		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dextrose;** Copy of certificate No. SD20170644 dated 12.01.2018 valid till 11.01.2023 issued by National Medical Product Administration is submitted. **Sodium Chloride;** Copy of certificate No. TT60-565-16-3 dated 28.07.2021 valid till 28.01.2023 issued by MEDSAFE New Zealand is submitted.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dextrose anhydrous;** Taken loan from M/s Atlantic Pharmaceutical Laboratories Peshawar. Batch No.: 202106156 Quantity: 48000Kg Invoice No.: KF2105111A Invoice date: 23.06.2021 Cleared by: AD I&E DRAP Peshawar **Sodium Chloride;** Taken loan from M/s Atlantic Pharmaceutical Laboratories Peshawar. Batch No. Mfg date: Exp date: Quantity: 24 metric tons Invoice No.: Invoice date: Cleared by:		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S	The S part in Module 3 is not provided. It is required for both drug substances.	The firm vide letter No. nil dated nil has submitted that *"S part has already been*

			submitted and approved in 323rd meeting of Registration Board for JHK-Sol DS 500ml & 100ml, JHK Sol-NS, JHK-Sol 5% & 10%. However copy of DMF has been enclosed for kind reference" The firm has only submitted a single page reply. **No DMF is submitted with the letter**	
2.	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Unisol-DS1/2 Infusion) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required	The firm vide letter No. nil dated nil has submitted following details along with pictorial evidence; Unisol DS1/2, Batch No. 3011039 **Mfg: 01.2023**, EXP 12.2025 Manufacturer: Unisa Pharma.	
3.	3.2.P.5.3	Verification of analytical procedures is not submitted.	The firm has submitted that they have already submitted it dossiers of JHK Sol DS 500ml & 1000ml and is attached for reference. The reply is a single page only, the firm has not submitted the verification studies of analytical procedures.	
4.	3.2.P.8	Submit studies conducted for potential water loss from your primary container (semipermeable LDPE container) as per ICH guidelines [ICH Q1A(R2)].	The firm has stated that for test of water loss, fill volume test has been relied upon since applied product has same solutes as already approved for JHK-SOL-DS	
5.	3.2.P.8	Submitted copies of executed BMRs of trial batches.	Submitted	
6.	3.2.P.8	The copy of invoice of Sodium chloride is not readable. Its clear copy is required.	Submitted	

Decision: The board deliberated on the matter and keeping in view the fact that products of the firm have already been approved in 323rd meeting of RB on basis of data submitted in S part of the dossier, the board approved the application of "JHK-Sol DS1/2 500ml IV Infusion.".

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

290.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals (Pvt)Ltd. Plot No. 34, St. no. NS-2, National industrial Zone, Rawat (DML No. 000927)**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals (Pvt) Ltd. Plot No. 34, St. no. NS-2, National industrial Zone, Rawat. DML No. 000927.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	Copy of approval of capsule section vide letter No. 1-5/2020-Lic dated 19.02.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23764 dated 27.09.2023
	Details of fee submitted	PKR 30,000/- Slip No. 2723254731 dated 19.09.2023
	The proposed proprietary name / brand name	**PRENAG 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Pregabalin… 50mg
	Pharmacotherapeutic Group of (API)	Gabapentinoids ATC Code: N02BF02
	Pharmaceutical form of applied drug	White to off-white powder filled in hard gelatin capsule shell of red colour size 2.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pregabalin Noumed 50 mg capsules MHRA Approved.
	For generic drugs (me-too status)	Gabica 50mg Capsule Reg. No. 048725 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	Name and address of API manufacturer.	M/s ALMELO Pvt. Ltd. Plot No. A-38, A-39 Road No. 7, IDA, Kukatpally, Gandhi Nagar Hyderabad, Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. PGB03521AL
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3

	(Conditions & duration of Stability studies)	batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. PEF-H-18-003, PEF-H-18-004, PEF-H-18-005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Prenag 50mg Capsule. **Reference product:** Lyrica 50mg Capsule, Batch No._____. mfg.:_____, Exp. _____ manufactured by M/s Pfizer Pakistan Pictorial evidence not submitted.. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 99.42 **At pH 4.5:** F2 = 97.52 **At pH 6.8:** F2 = 95.12
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s ALMELO Pvt. Ltd. Plot No. A-38, A-39 Road No. 7, IDA, Kukatpally, Gandhi Nagar Hyderabad, Telangana India.		
API Lot No.	PGB03521AL		
Description of Pack (Container closure system)	Hard gelatin capsules packed in Alu-alu blister. Blisters are packed in bleach card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	20.12.2021	21.12.2021	22.12.2021

No. of Batches		3
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 42177/TS/2020 dated 13.09.2020 valid till 03.09.2021 issued by Drug Control Administration Telangana is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Pregabalin** Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of valid GMP certificate of drug substance manufacturer is required.	The firm vide letter No. nil dated nil has submitted valid GMP certificate of drug substance manufacturer. Certificate No. 122351/TS/2023 dated 01.07.2023 valid till 29.06.2024. Issued by drugs control administration Telangana State India.
2.	-	Copy of clearance certificate of drug substance issued by DRAP field office is required.	The firm has submitted copy of clearance certificate issued by AD I&E DRAP Islamabad. Batch No. PGB03521AL, Invoice No. APL/023/21/22 dated 11.08.2021 Quantity 15kg
3.	3.2.P.2	The batch number, manufacturing date and expiry date of reference product (Lyrica) is not submitted. Further also submit pictorial evidence of reference product.	Pictorial evidence is submitted. Lyrica 75mg batch No. GE0988 mfg 03.2022 exp 02.2025 manufactured by M/s Pfizer Germany. Imported by Pfizer Pakistan. Pictorial evidence of 50mg strength and its details are not submitted The firm vide another letter have informed that pack of 50mg reference product are lost.

4.	3.2.P.5	The monograph of drug product is available in British Pharmacopoeia and specifications of applied product are innovator. Justify.	No response submitted	
5.	3.2.P.8	The chromatograms submitted are printed in such a way that majority of information is obscured. Copies of chromatograms having all the information are required.	No response submitted	
6.	3.2.P.8	Copies of executed BMRs of trial batches are required.	Copies of BMR of trial batches T001, T002 & T003 are submitted.	

Decision: Approved.
The registration letter will be issued after submission of readable copies of the chromatograms and associated analytical record.

291.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals (Pvt)Ltd. Plot No. 34, St. no. NS-2, National industrial Zone, Rawat (DML No. 000927)**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals (Pvt) Ltd. Plot No. 34, St. no. NS-2, National industrial Zone, Rawat. DML No. 000927.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of capsule section vide letter No. 1-5/2020-Lic dated 19.02.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23765 dated 27.09.2023
	Details of fee submitted	PKR 30,000/- Slip No. 91363359 dated 19.09.2023
	The proposed proprietary name / brand name	**PRENAG 75mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Pregabalin… 75mg
	Pharmacotherapeutic Group of (API)	Gabapentinoids ATC Code: N02BF02
	Pharmaceutical form of applied drug	White to off-white powder filled in hard gelatin capsule shell of blue colour size 2.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pregabalin Amarox 75 mg capsules MHRA Approved.

	For generic drugs (me-too status)	Gabica 75mg Capsule Reg. No. 047365 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	Name and address of API manufacturer.	M/s ALMELO Pvt. Ltd. Plot No. A-38, A-39 Road No. 7, IDA, Kukatpally, Gandhi Nagar Hyderabad, Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. PGB03521AL
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. PEF-H-18-003, PEF-H-18-004, PEF-H-18-005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Prenag 75mg Capsule. **Reference product:** Lyrica 75mg Capsule, Batch No._____. mfg.:_____, Exp. _____ manufactured by M/s Pfizer Pakistan Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:**

		<u>At pH 1.2:</u> F2 = 98.71 **<u>At pH 4.5:</u>** F2 = 97.22 **<u>At pH 6.8:</u>** F2 = 88.57
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s ALMELO Pvt. Ltd. Plot No. A-38, A-39 Road No. 7, IDA, Kukatpally, Gandhi Nagar Hyderabad, Telangana India.		
API Lot No.	PGB03521AL		
Description of Pack (Container closure system)	Hard gelatin capsules packed in Alu-alu blister. Blisters are packed in bleach card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	20.12.2021	21.12.2021	22.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 42177/TS/2020 dated 13.09.2020 valid till 03.09.2021 issued by Drug Control Administration Telangana is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Pregabalin** Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of valid GMP certificate of drug substance manufacturer is required.	The firm vide letter No. nil dated nil has submitted valid GMP certificate of drug substance manufacturer. Certificate No. 122351/TS/2023 dated 01.07.2023 valid till 29.06.2024. Issued by drugs control administration Telangana State India.
2.	-	Copy of clearance certificate of drug substance issued by DRAP field office is required.	The firm has submitted copy of clearance certificate issued by AD I&E DRAP Islamabad. Batch No. PGB03521AL, Invoice No. APL/023/21/22 dated 11.08.2021 Quantity 15kg
3.	3.2.P.2	The batch number, manufacturing date and expiry date of reference product (Lyrica) is not submitted. Further also submit pictorial evidence of reference product.	Pictorial evidence is submitted. Lyrica 75mg batch No. GE0988 mfg 03.2022 exp 02.2025 manufactured by M/s Pfizer Germany. Imported by Pfizer Pakistan.
4.	3.2.P.5	The monograph of drug product is available in British Pharmacopoeia and specifications of applied product are innovator. Justify.	No response submitted.
5.	3.2.P.8	Copies of executed BMRs of trial batches are required.	Copies of BMR of trial batches T001, T002 & T003 are submitted.

Decision: Keeping in view the guidance issued vide letter No. 9-2/2022-PEC dated 18.12.2023, the Board approved the application of "PRENAG 75mg Capsule" with innovator specifications.

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

292.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals (Pvt)Ltd. Plot No. 34, St. no. NS-2, National industrial Zone, Rawat (DML No. 000927)**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals (Pvt) Ltd. Plot No. 34, St. no. NS-2, National industrial Zone, Rawat. DML No. 000927.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval of capsule section vide letter No. 1-5/2020-Lic dated 19.02.2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23766 dated 27.09.2023
	Details of fee submitted	PKR 30,000/- Slip No. 5268822962 dated 19.09.2023
	The proposed proprietary name / brand name	**PRENAG 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Pregabalin… 100mg
	Pharmacotherapeutic Group of (API)	Gabapentinoids ATC Code: N02BF02
	Pharmaceutical form of applied drug	White to off-white powder filled in hard gelatin capsule shell of green/white colour size 2.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PREGABALIN NOUMED 100 MG CAPSULES MHRA Approved.
	For generic drugs (me-too status)	Gabica 100mg Capsule Reg. No. 047366 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	Name and address of API manufacturer.	M/s ALMELO Pvt. Ltd. Plot No. A-38, A-39 Road No. 7, IDA, Kukatpally, Gandhi Nagar Hyderabad, Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. PGB03521AL
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at

		30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. PEF-H-18-003, PEF-H-18-004, PEF-H-18-005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Prenag 100mg Capsule. **Reference product:** Lyrica 100mg Capsule, Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 95.15 **At pH 4.5:** F2 = 91.39 **At pH 6.8:** F2 = 82.42
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s ALMELO Pvt. Ltd. Plot No. A-38, A-39 Road No. 7, IDA, Kukatpally, Gandhi Nagar Hyderabad, Telangana India.		
API Lot No.	PGB03521AL		
Description of Pack (Container closure system)	Hard gelatin capsules packed in Alu-alu blister. Blisters are packed in bleach card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	20.12.2021	21.12.2021	22.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 42177/TS/2020 dated 13.09.2020 valid till 03.09.2021 issued by Drug Control Administration Telangana is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Pregabalin** Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of valid GMP certificate of drug substance manufacturer is required.	The firm vide letter No. nil dated nil has submitted valid GMP certificate of drug substance manufacturer. Certificate No. 122351/TS/2023 dated 01.07.2023 valid till 29.06.2024. Issued by drugs control administration Telangana State India.
2.	-	Copy of clearance certificate of drug substance issued by DRAP field office is required.	The firm has submitted copy of clearance certificate issued by AD I&E DRAP Islamabad. Batch No. PGB03521AL, Invoice No. APL/023/21/22 dated 11.08.2021 Quantity 15kg
3.	3.2.P.2	The batch number, manufacturing date and expiry date of reference product (Lyrica) is not submitted. Further also submit pictorial evidence of reference product.	Pictorial evidence is submitted. Lyrica 75mg batch No. GE0988 mfg 03.2022 exp 02.2025 manufactured by M/s Pfizer Germany. Imported by Pfizer Pakistan. Pictorial evidence of 100mg strength and its details are not submitted. The firm has also informed that they have lost the pack of reference product.
4.	3.2.P.5	The monograph of drug product is available in British Pharmacopoeia and specifications of applied product are innovator. Justify.	No response submitted.

5.	3.2.P.8	Copies of executed BMRs of trial batches are required.	Copies of BMR of trial batches T001, T002 & T003 are submitted.	

Decision: Keeping in view the guidance issued vide letter No. 9-2/2022-PEC dated 18.12.2023, the board approved the application of "PRENAG 100mg Capsule" with innovator specifications.

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

Case no. 02 Registration applications of contract manufacturing

293.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore. DML No. 000863.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26.02.2020 valid till 12.02.2022 issued by DRAP Lahore in favour of M/s Bio-Mark is provided. (Firm has applied for new GMP certificate) Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3220 dated 03.02.2023
	Details of fee submitted	PKR 75,000/- Slip No. 40961161 dated 19.12.2022
	The proposed proprietary name / brand name	**MITZAP 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Mirtazapine…….15mg
	Pharmacotherapeutic Group of (API)	Other antidepressants. ATC Code: N06AX11
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	For generic drugs (me-too status)	Mirtazep 15mg tablet Reg. No. 024215 M/s Zafa Pharmaceutical Labs Karachi.
	Name and address of API manufacturer.	M/s Maithri Drugs Pvt. Ltd. Sy. No. 205, 222 to 226, IDA Bonthapally, Bonthapally(village) Gummadidala (Mandal) Sangareddy District, Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. MZ0090521
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. MZ0010118, MZ0020118, MZ0030118
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Mtpine 15mg Batch No. PTLAM-001 mfg 02-2020. **Reference product:** Mirtazep 15mg Tablets, Batch No. ZFM/117. mfg.: -, Exp. 05.2023 manufactured by M/s Zafa Karachi. Pictorial evidence is submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = more than 85% in 15 min **At pH 4.5:** F2 = more than 85% in 15 min

		At pH 6.8: F2 = 69
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Maithri Drugs Pvt. Ltd. Sy. No. 205, 222 to 226, IDA Bonthapally, Bonthapally(village) Gummadidala (Mandal) Sangareddy District, Telangana India.		
API Lot No.	MZ0090521		
Description of Pack (Container closure system)	Film coated purple color round biconvex tablet in Alu-Alu blister with leaflet pack in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22D286	20M382	22D286
Batch Size	100,000 tablets	100,000 tablets	100,000 tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	03.2022	03.2022	03.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 3885/E1/2019 valid till 10.02.2023 issued by DCA Telangana State India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Mirtazapine** Batch No.: MZ0090521 Mfg date: 05.2021 Quantity: 5Kg Invoice No.: 6500215068 Invoice date: 23.09.2021 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.		
294.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore. DML No. 000863.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26.02.2020 valid till 12.02.2022 issued by DRAP Lahore in favour of M/s Bio-Mark is provided. (Firm has applied for new GMP certificate) Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 2983 dated 01.02.2023
	Details of fee submitted	PKR 75,000/- Slip No. 466516972 dated 19.12.2022
	The proposed proprietary name / brand name	**MITZAP 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Mirtazapine…….30mg
	Pharmacotherapeutic Group of (API)	Other antidepressants. ATC Code: N06AX11
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	For generic drugs (me-too status)	Mirtazep 30mg tablet Reg. No. 024216 M/s Zafa Pharmaceutical Labs Karachi.
	Name and address of API manufacturer.	M/s Maithri Drugs Pvt. Ltd. Sy. No. 205, 222 to 226, IDA Bonthapally, Bonthapally(village) Gummadidala (Mandal) Sangareddy District, Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. MZ0090521
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. MZ0010118, MZ0020118, MZ0030118
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Mtpine 15mg Batch No. PTLAM-001 mfg 02-2020. **Reference product:** Mirtazep 30mg Tablets, Batch No. ZFH/658. mfg.: -, Exp. 05.2023 manufactured by M/s Zafa Karachi. Pictorial evidence is submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = more than 85% in 15 min **At pH 4.5:** F2 = more than 85% in 15 min **At pH 6.8:** F2 = 69
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Maithri Drugs Pvt. Ltd. Sy. No. 205, 222 to 226, IDA Bonthapally, Bonthapally(village) Gummadidala (Mandal) Sangareddy District, Telangana India.
API Lot No.	MZ0300720
Description of Pack	Film coated light yellow color round biconvex tablet in Alu-Alu blister with

(Container closure system)	leaflet pack in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20M381	20M383	20M285
Batch Size	100,000 tablets	100,000 tablets	100,000 tablets
Manufacturing Date	06.2021	06.2021	06.2021
Date of Initiation	06.2021	06.2021	06.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 3885/E1/2019 valid till 10.02.2023 issued by DCA Telangana State India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Mirtazapine** Batch No.: MZ0300720 Mfg date: 06.2020 Quantity: 5kg Invoice No.: 6500205072 Invoice date: 23.10.2020 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

295.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the firm	Copy of GMP certificate No. 37/2022-DRAP(AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided. Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 issubmitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1373 dated 16.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 88676519 dated 20.12.2022
	The proposed proprietary name / brand name	**APLAST 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apremilast..... 10mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants ATC Code: L04AA32
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	<u>Two weeks' starter pack;</u> 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets <u>28 days' starter pack;</u> 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets Additional 30mg tablets: 42 tablets.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OTEZLA 20 MG FILM-COATED TABLETS, OTEZLA 10 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Glen Mark Life Sciences Limited (701214), A-80, MIDC, Kurkumbh, Tal, D/UND-413802, Dist-Pune Zone 4, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 83220730
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 83151223, 83151300, 83151315
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Aprimelast 10mg Tablet Batch No. PTAML-001 mfg 06-2022. **Reference product:** Otezla 10mg tablets, Batch No. 2655A. mfg.: -, Exp. 05.2023anufactured by M/s Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 79 **At pH 4.5:** F2 = 83 **At pH 6.8:** F2 = 71
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Glen Mark Life Sciences Limited (701214), A-80,, MIDC, Kurkumbh, Tal, D/UND-413802, Dist-Pune Zone 4, Maharashtra India.
API Lot No.	83220110
Description of Pack (Container closure system)	A film coated yellow colour oval shaped, tablet, plain on both sides, packed in alu-alu blister, packed in unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	AML-002	AML-001	-
Batch Size	5000 tablets	5000 tablets	-
Manufacturing Date	06.2022	06.2022	-
Date of Initiation	28.06.2022	28.06.2022	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 6104231 dated 25.01.2022 valid till 24.01.2023 issued by FDA Maharashtra India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Apremilast** Batch No.: 83220730 Mfg date: Exp date: Quantity: 700gm Invoice No.: 8009/SR/ROW/22-23 Invoice date: 18.01.2022 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	The copy of manufacturing license of drug substance manufacturer does not list Apremilast. Clarify.	The firm vide letter No. CCL/23/E-188 dated 13.12.2023 has submitted their reply. Copy of License No. 1098963 dated 14.08.2022 issued by FDA Maharashtra is submitted. In license Apremilast is mentioned.
2.	3.2.P.2.2	The manufacturer of reference product used in pharmaceutical equivalence (Otezla) is not mentioned. Further pictorial evidence of reference product is also required.	Submitted. Otzela, product of Amgen GmbH Netherlands. Batch No. F2684A
3.	3.2.P.8	Accelerated and real time stability studiesdata of drug product at 3rd time point (6th month) are not submitted.	Complete stability data for 6 months is submitted.

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.		
296.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 37/2022-DRAP(AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided. Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 issubmitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1374 dated 16.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 80432977 dated 20.12.2022
	The proposed proprietary name / brand name	**APLAST 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apremilast..... 20mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants ATC Code: L04AA32
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	Two weeks' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets 28 days' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets Additional 30mg tablets: 42 tablets.
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	OTEZLA 20 MG FILM-COATED TABLETS, OTEZLA 10 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Glen Mark Life Sciences Limited (701214), A-80, MIDC, Kurkumbh, Tal, D/UND-413802, Dist-Pune Zone 4, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 83220730
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 83151223, 83151300, 83151315
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Aprimelast 20mg Tablet Batch No. PTAMM-001 mfg 06-2022. **Reference product:** Otezla 20mg tablets, Batch No. 2684A. mfg.: -, Exp. 05.2023anufactured by M/s Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 81 **At pH 4.5:** F2 = ____ **At pH 6.8:** F2 = 91
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug

		product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Glen Mark Life Sciences Limited (701214), A-80,, MIDC, Kurkumbh, Tal, D/UND-413802, Dist-Pune Zone 4, Maharashtra India.		
API Lot No.	83220730		
Description of Pack (Container closure system)	A film coated pink colour oval shaped, tablet, plain on both sides, packed in alu-alu blister, packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AMM-001	AMM-002	-
Batch Size	5000 tablets	5000 tablets	-
Manufacturing Date	06.2022	06.2022	-
Date of Initiation	01.07.2022	01.07.2022	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 6104231 dated 25.01.2022 valid till 24.01.2023 issued by FDA Maharashtra India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Apremilast** Batch No.: 83220730 Mfg date: Exp date: Quantity: 700gm Invoice No.: 8009/SR/ROW/22-23 Invoice date: 18.01.2022 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	The copy of manufacturing license of drug substance manufacturer does not list Apremilast. Clarify.	The firm vide letter No. CCL/23/R-189 dated 13.12.2023 has submitted theirreply. Copy of License No. 1098963 dated 14.08.2022 issued by FDA Maharashtra is

			submitted. In license Apremilast is mentioned.
2.	3.2.P.2.2	The manufacturer of reference product used in pharmaceutical equivalence (Otezla) is not mentioned. Further pictorial evidence of reference product is also required.	Submitted. Otzela, product of Amgen GmbH Netherlands. Batch No. F2684A Same pack contains multiple strengths that's why batch No. of multiple strengths are same.
3.	3.2.P.2.2	In comparative dissolution profile, F2 factor calculation at pH 4.5 is not submitted.	Submitted. Results are comparable with reference product.
4.	3.2.P.8	Accelerated and real time stability studies data of drug product at 3rd time point (6th month) are not submitted.	Complete stability data for 6 months is submitted.

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

297.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 37/2022-DRAP(AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided. Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 issubmitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1374 dated 16.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 9025168995 dated 21.12.2022
	The proposed proprietary name / brand name	**APLAST 30mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apremilast..... 30mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants ATC Code: L04AA32
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	Two weeks' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets 28 days' starter pack; 13 Tablet blister pack containing 10mg 4 tablets 20mg 4 tablets 30mg 5 tablets Additional 30mg tablets: 42 tablets. **28's, 60's, 500's,**
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Otezla 30 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Glen Mark Life Sciences Limited (701214), A-80, MIDC, Kurkumbh, Tal, D/UND-413802, Dist-Pune Zone 4, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 83220730
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Batch No. 83151223, 83151300, 83151315
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Aprimelast 30mg Tablet Batch No. PTAMH-001 mfg 06-2022. **Reference product:** Otezla 30mg tablets, Batch No. F2663AA. mfg.: -, Exp. 05.2023anufactured by M/s Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 88 **At pH 4.5:** F2 = 98 **At pH 6.8:** F2 = 72
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Glen Mark Life Sciences Limited (701214), A-80,, MIDC, Kurkumbh, Tal, D/UND-413802, Dist-Pune Zone 4, Maharashtra India.		
API Lot No.	83220730		
Description of Pack (Container closure system)	A film coated blue colour oval shaped, tablet, plain on both sides, packed in alu-alu blister, packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AMH-001	AMH-002	-
Batch Size	5000 tablets	5000 tablets	-
Manufacturing Date	06.2022	06.2022	-
Date of Initiation	03.07.2022	03.07.2022	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 6104231 dated 25.01.2022 valid till 24.01.2023 issued by FDA Maharashtra India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Apremilast** Batch No.: 83220730 Mfg date: Exp date: Quantity: 700gm Invoice No.: 8009/SR/ROW/22-23 Invoice date: 18.01.2022 Cleared by: AD I&E DRAP Lahore.

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply.
1.	-	The copy of manufacturing license of drug substance manufacturer does not list Apremilast. Clarify.	The firm vide letter No. CCL/23/R-190 dated 13.12.2023 has submitted their reply. Copy of License No. 1098963 dated 14.08.2022 issued by FDA Maharashtra is submitted. In license Apremilast is mentioned.
2.	3.2.P.2.2	The manufacturer of reference product used in pharmaceutical equivalence (Otezla) is not mentioned. Further pictorial evidence of reference product is also required.	Submitted. Otzela, product of Amgen GmbH Netherlands. Batch No. F2684A Batch No. is same for multiple strengths because packs having multiple strengths were used.
3.	3.2.P.8	Accelerated and real time stability studies data of drug product at 3rd time point (6th month) are not submitted.	Complete stability data for 6 months is submitted.

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

298.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 37/2022-DRAP(AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided. Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.

	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 issubmitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 2740 dated 31.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 04548082020 dated 20.12.2022
	The proposed proprietary name / brand name	**ELIX 150mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Elagolix sodium eq to Elagolix…. 150mg
	Pharmacotherapeutic Group of (API)	Anti-gonadotropin-releasing hormones ATC Code: H01CC03
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	54's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Orilissa 150mg & 200mg USFDA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Biophore India Pharmaceuticals Pvt. Ltd. Plot No. 80A, Road No. 5, JNPC E, Bonangi (V) Parawada (M) Visakhapatnam, AP, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 6024/3/001/21
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.

		Batch No. 6024/3/001/20, 6024/3/002/20, 6024/3/003/20
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Elagolix 150mg Tablet Batch No. ELXL-001 mfg 04-2022. **Reference product:** Orilissa 150mg tablets, Batch No. 100028815. mfg.: -, Exp. 07.2023 manufactured by M/s Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 92 **At pH 4.5:** F2 = 98 **At pH 6.8:** F2 = 72
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Biophore India Pharmaceuticals Pvt. Ltd. Plot No. 80A, Road No. 5, JNPC E, Bonangi (V) Parawada (M) Visakhapatnam, AP, India.		
API Lot No.	6024/3/001/21		
Description of Pack (Container closure system)	A film coated white colour oblong tablet, packed in alu-alu blister, packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ELXL-001	ELXL-002	ELXL-003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04.2022	04.2022	04.2022
Date of Initiation	18.04.2022	18.04.2022	18.04.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 375/DD/DCA/VSP/2022dated 09.03.2021 valid till 08.03.2022 issued by Drug Control Administration Andhrapradesh India is submitted.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Elagolix Sodium** Batch No.: 6024/3/001/21 Mfg date: 20.10.2021 Exp date: 19.10.2023 Quantity: 2Kg Invoice No.: BPVC/21-22/77E Invoice date: 07.12.2021 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	The applied drug product (Elagolix) is a selective competitive antagonist of Gonadotropin-releasing hormone receptor(GnRHR), this is receptor of gonadotropin-releasing hormone. Justify manufacturing of this product in general tablet section.	The firm vide letter No. CCL/23/R-186 dated 13.12.2023 has submitted their reply. Firm has submitted that product will be manufactured in Tablet general section.
2.	-	The list of API for which drug substance manufacturer is authorized is not attached with copy of its manufacturing authorization.	Copy of permission to manufacture Elagolix Sodium for export to Pakistan is submitted. Issued by Drugs Control Administration Andhra Pradesh.
3.	3.2.P.2.2	The manufacturer of reference product used in pharmaceutical equivalence (Orilissa) is not mentioned. Further pictorial evidence of reference product is also required.	Submitted. Orilissa 150mg, product of M/s Abbvie Inc North Chicago USA. Batch No. 100028815
4.	3.2.P.8	Accelerated and real time stability studies data of drug product at 3rd time point (6th month) are not submitted.	Complete stability data for 6 months is submitted.

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

299.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 37/2022-DRAP(AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided. Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 issubmitted.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1372 dated 16.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 08367468 dated 20.12.2022
	The proposed proprietary name / brand name	**ELIX 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Elagolix sodium eq to Elagolix…. 200mg
	Pharmacotherapeutic Group of (API)	Anti-gonadotropin-releasing hormones ATC Code: H01CC03
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	54's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Orilissa 150mg & 200mg USFDA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Biophore India Pharmaceuticals Pvt. Ltd. Plot No. 80A, Road No. 5, JNPC E, Bonangi (V) Parawada (M) Visakhapatnam, AP, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance. Batch No. 6024/3/001/21
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. 6024/3/001/20, 6024/3/002/20, 6024/3/003/20
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Elagolix 200mg Tablet Batch No. ELXh-001 mfg 04-2022. **Reference product:** Orilissa 200mg tablets, Batch No. 100038816. mfg.: -, Exp. 08.2023 manufactured by M/s Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 96 **At pH 4.5:** F2 = 94 **At pH 6.8:** F2 = 87
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Biophore India Pharmaceuticals Pvt. Ltd. Plot No. 80A, Road No. 5, JNPC E, Bonangi (V) Parawada (M) Visakhapatnam, AP, India.		
API Lot No.	6024/3/001/21		
Description of Pack (Container closure system)	A film coated white colour oblong tablet, packed in alu-alu blister, packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ELXH-001	ELXH-002	ELXH-003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04.2022	04.2022	04.2022
Date of Initiation	22.04.2022	22.04.2022	23.04.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 375/DD/DCA/VSP/2022dated 09.03.2021 valid till 08.03.2022 issued by Drug Control Administration Andhrapradesh India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Elagolix Sodium** Batch No.: 6024/3/001/21 Mfg date: 20.10.2021 Exp date: 19.10.2023 Quantity: 2Kg Invoice No.: BPVC/21-22/77E Invoice date: 07.12.2021 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	-	The applied drug product (Elagolix) is a selective competitive antagonist of Gonadotropin-releasing hormone receptor(GnRHR), this is receptor of gonadotropin-releasing hormone. Justify manufacturing of this product in general tablet section.	The firm vide letter No. CCL/23/R-187 dated 13.12.2023 has submitted their reply. Firm has submitted that product will be manufactured in Tablet general section.
2.	-	The list of API for which drug substance manufacturer is authorized is not attached with copy of its manufacturing authorization.	Copy of permission to manufacture Elagolix Sodium for export to Pakistan is submitted. Issued by Drugs Control Administration Andhra Pradesh.
3.	3.2.P.2.2	The manufacturer of reference product used in pharmaceutical equivalence (Orilissa) is not mentioned. Further pictorial evidence of reference product is also required.	Submitted. Orilissa 200mg, product of M/s Abbvie Inc North Chicago USA. Batch No. 100038816
4.	3.2.P.8	Accelerated and real time stability studies data of drug product at 3rd time point (6th month) are not submitted.	Complete stability data for 6 months is submitted.

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

300.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. 35-A, Punjab Small Industrial Estate, Taxila. DML No. 000856.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 3-29/2019-Addl. Dir. (QA&LT-I)-59 dated 17.08.2022 valid till 15.08.2024 issued by DRAP Islamabad in favour of M/s Horizon is provided. Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1372 dated 16.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 311345418265 dated 21.12.2022
	The proposed proprietary name / brand name	**RETIM Ointment 10mg (1%w/w)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains; Retapamulin…..... 10mg
	Pharmacotherapeutic Group of (API)	Other antibiotics for topical use ATC Code: D06AX13
	Pharmaceutical form of applied drug	Topical Ointment.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Altabax 1% Topical Ointment USFDA Approved.
	For generic drugs (me-too status)	Altargo Ointment Reg. No. 080986 M/s GSK Karachi
	Name and address of API manufacturer.	M/s Sumar Biotech LLP, Plot No. 112, 113, 114 GIDC Estate Gozariya, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. SBL/SRD/RTP/19/08/061
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months. Batch No. SPL/SRD/RTP/19/08/046, SPL/SRD/RTP/19/08/047, SPL/SRD/RTP/19/08/048.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Retapamulim ointment 1% Batch No. RTP-PT001 mfg 03-2022. **Reference product:** Altabax ointment 1%, Batch No. 800121. mfg.: -, Exp. 05.2023 manufactured by M/s Pictorial evidence not submitted. **Tests done:** physical characteristics, minimum fill, identification, Assay, organic impurities, uniformity of content and microbial test.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sumar Biotech LLP, Plot No. 112, 113, 114 GIDC Estate Gozariya, Gujrat, India.		
API Lot No.	SBL/SRD/RTP/19/08/061		
Description of Pack (Container closure system)	White to almost white ointment filled in aluminium tubes sealed with aluminium seal and capped with screw plastic cap.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RTP-001	RTP-002	-

Batch Size	500 tubes	500 tubes	-
Manufacturing Date	03.2022	03.2022	-
Date of Initiation	01.04.2022	01.04.2022	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. S-GMP20102262 valid till 06.10.2022 issued by FDA Gujrat state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Retapamulin** Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by:
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	
1.	-	Section approval letter of drug product manufacturer is required.	The firm vide letter No. CCL/23/R-192 dated 13.12.2023 has submitted their reply. Firm has submitted copy of section approval letter of M/s HorizonHeatlhcare (Pvt.) Ltd. Vide No. 1-17/2012-Lic (Vol-III) dated 25.10.2023 wherein Cream/ointment/Gel (General) Section is mentioned.
2.	-	The list of API for which drug substance manufacturer is authorized is not attached with copy of its manufacturing authorization.	Copy of permission to manufacture Retapamulin is submitted. Issued by FDA Gujrat India.
3.	-	Clearance documents of drug substance are required. (AD attested invoice or clearance certificate)	Copy of import license dated 17.02.2022 is submitted. Issued by AD I&E DRAP Islamabad.
4.	3.2.P.2.2	The manufacturer of reference product used in pharmaceutical equivalence (Altabax) is not mentioned. Further pictorial evidence of reference product is also required.	Submitted. Altabax 1% ointment, product of M/s GSK. Batch No. 800121

5.	3.2.P.8	Accelerated and real time stability studies data of drug product at 3rd time point (6th month) are not submitted.	Complete stability data for 6 months is submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter.**

301.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceutical (Pvt.) Ltd. 62-Industrial estate, Kot Lakhpat, Lahore. (DML No. 000052)**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33, Sunder Industrial Estate Lahore. DML No. 000782.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 37/2022-DRAP(AD-98034851686) dated 28.03.2022 valid till 14.10.2023 issued by DRAP Lahore in favour of M/s Horizon is provided. Copy of GMP certificate No. 118/2019-DRAP (AD-789112-762) dated 13.05.2019 valid till 29.04.2022 issued by DRAP Lahore in favour of M/s CCL is provided.
	Evidence of approval of manufacturing facility	Copy of approval of Tablet (General) vide letter No. 1-51/2004-Lic (Vol-I) dated 07.06.2022 issubmitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 854 dated 10.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 875476929634 dated 20.12.2022
	The proposed proprietary name / brand name	**AZILSA 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Azilsartan Medoxomil Potassium eq to Azilsartan medoxomil 20mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain ATC Code: C09CA09
	Pharmaceutical form of applied drug	Uncoated tablet
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	14, 28, 30, 56, 90, 98
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EDARBI 20 MG TABLETS

		MHRA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s CTX Lifesciences, Pvt. Ltd. Block No. 251-252, Sachin-Magdalla Road, GIDC Sachin , Surat, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 19AK00013
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 months. Batch No. AK18002, AK18003, AK18004
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Azilsartan 20mg Tablet Batch No. PTLAM-001 mfg 02-2020. **Reference product:** Edarbi 20mg Tablets, Batch No. 473810. mfg.: -, Exp. 01.2022 manufactured by M/s Pictorial evidence not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 91 **At pH 4.5:** F2 = 99 **At pH 6.8:** F2 = 95
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s CTX Lifesciences, Pvt. Ltd. Block No. 251-252, Sachin-Magdalla Road, GIDC Sachin , Surat, Gujrat India.		
API Lot No.	19AK00013		
Description of Pack (Container closure system)	White to off-white colour, round, biconvex tablet in alu alu blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LAM-001	LAM-002	LAM-003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	03.2020	04.2020	04.2020
Date of Initiation	24.03.2020	02.04.2020	06.04.2020
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 19061470 valid till 01.07.2022 issued by FDA Gujrat State India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Azilsartan Medoxomil Potassium** Batch No.: 19AK00013 Mfg date: 01.02.2019 Quantity: 1.5kg Invoice No.: EI/3092100609 Invoice date: 31.12.2019 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2	The manufacturer of reference product used in pharmaceutical equivalence (Edarbi) is not mentioned. Further pictorial evidence of reference product is also required.	The firm has replied vide letter No. CCL/23/R-191 dated 13.12.2023 Submitted. Edarbi 20mg Tablets. Manufactured by M/s Takeda Pharmaceutical Company Ltd. Lot No. 473810
2.	3.2.P.8	Accelerated and real time stability studies data of drug product at 3rd time point (6th month) are not submitted.	Complete data of stability for 6 months is submitted.

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**		
302.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi industrial area, Karachi. (DML No. 000140)**
	Name, address of Manufacturing site.	M/s Wood Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi. DML No. 000042
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 142/2018-DRAP (K) dated 28.12.2018 valid till 27.12.2019 issued by DRAP Karachi in favour of M/s WoodwardsPakistan is provided.
	Evidence of approval of manufacturing facility	Not submitted. Only a copy of inspection report mentioning Capsule Cephalosporin section is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1558 dated 17.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 81335098361 dated 04.01.2023
	The proposed proprietary name / brand name	**ZOOKA 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Cefixime (Compacted)..... 400mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins. ATC Code: J01DD08
	Pharmaceutical form of applied drug	0 size white & purple capsule containing off white powder.
	Reference to Finished product specifications	**JP Specifications.**
	Proposed Pack size	5’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 400mg Capsule USFDA Approved.
	For generic drugs (me-too status)	Cefspan 400mg Capsule Reg. No. 013860 M/s Barrett Hodgson
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 00243/044/2022
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 00244/135/2010, 00243/135/2010, 00244/137/2010.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** ZOOKA 400mg Capsule **Reference product:** Cefiget 400mg, manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, weight variation, DT, uniformity of dosage unit, dissolution and assay **CDP:** **At pH 1.2:** F2 = 77 **At pH 4.5:** F2 = 84 **At pH 7.2:** F2 = 74
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
API Lot No.	00243/044/2022
Description of Pack (Container closure system)	0 size white & purple capsule containing off white powder.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	5WC400	5WC401	5WC402
Batch Size	75000 capsules	75000 capsules	75000 capsules
Manufacturing Date	05.2022	05.2022	05.2022
Date of Initiation	05.2022	05.2022	05.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Copy of section approval letter of drug product manufacturer is required.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.
3.	1.4.3.3	Copy of latest and valid GMP certificate of drug product manufacturer is required.
4.	-	The applied label is of Cefixime compacted 400mg. The salt or hydrate form is not mentioned. Label claim needs to be revised as per innovator product along with requisite fee.
5.	3.2.P.2	CDP is done at pH 1.2, 4.5 and 7.2. Justify doing CDP at pH 7.2 instead 6.8.
6.	3.2.P.2	Batch No and expiry date of reference product (Cefiget) is not mentioned. Also provide pictorial evidence of the reference product.
7.	3.2.P.5	Specifications of JP are applied.
8.	3.2.P.8	Audit trail of HPLC is required.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

303.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi industrial area, Karachi. (DML No. 000140)**
	Name, address of Manufacturing site.	M/s Wood Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi. DML No. 000042
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 142/2018-DRAP (K) dated 28.12.2018 valid till 27.12.2019 issued by DRAP Karachi in favour of M/s WoodwardsPakistan is provided.
	Evidence of approval of manufacturing facility	Not submitted. Only a copy of inspection report mentioning Capsule Cephalosporin section is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1556 dated 17.01.2023
	Details of fee submitted	PKR 75,000/- Slip No. 9802677893 dated 17.10.2022
	The proposed proprietary name / brand name	**ZOOKA 100mg/5ml Powder for oral suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cefixime (as trihydrate) 100mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins. ATC Code: J01DD08
	Pharmaceutical form of applied drug	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.
	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	Cefixime 100 mg/5 ml granules for oral suspension (cefixime) - UK/H/5626/001/DC; PL 40168/0005 MHRA Approved.
	For generic drugs (me-too status)	Cefiget Powder for Oral Suspension Reg. No. 045119 M/s Getz Pharma
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 00243/044/2022
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 00244/135/2010, 00243/135/2010, 00244/137/2010.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** ZOOKA 100mg Suspension **Reference product:** Cefiget 100mg/5ml, Batch No. 286. mfg.: 03.2022, Exp. 03.2024 manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, weight variation, uniformity of dosage unit and assay **CDP:** **At pH 1.2:** F2 = 80 **At pH 4.5:** F2 = 92 **At pH 7.2:** F2 = 74
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.		
API Lot No.	00243/044/2022		
Description of Pack (Container closure system)	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	4WD100	4WD101	4WD102
Batch Size	6666 bottles	6666 bottles	6666 bottles
Manufacturing Date	04.2022	04.2022	04.2022
Date of Initiation	04.2022	04.2022	04.2022
No. of Batches	3		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

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

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Copy of section approval letter of drug product manufacturer is required.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.
3.	3.2.P.2	Pictorial evidence of the reference product used in pharmaceutical equivalence is required.
4.	3.2.P.8	Chromatograms submitted are not visible. Clear copies of chromatograms are required.
5.	3.2.P.8	Audit trail of HPLC is required.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

304.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi industrial area, Karachi. (DML No. 000140)**
	Name, address of Manufacturing site.	M/s Wood Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi. DML No. 000042
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 142/2018-DRAP (K) dated 28.12.2018 valid till 27.12.2019 issued by DRAP Karachi in favour of M/s WoodwardsPakistan is provided.
	Evidence of approval of manufacturing facility	Not submitted. Only a copy of inspection report mentioning Capsule Cephalosporin section is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1557 dated 17.01.2023
	Details of fee submitted	PKR 75,000/-

		Slip No. 632691643 dated 17.10.2022
	The proposed proprietary name / brand name	**ZOOKA DS 200mg/5ml Powder for oral suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cefixime (as trihydrate) 200mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins. ATC Code: J01DD08
	Pharmaceutical form of applied drug	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.
	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	SUPRAX 200mg/5ml For suspension, Lupin USFDA Approved.
	For generic drugs (me-too status)	Cefiget DS Powder for Oral Suspension Reg. No. 045120 M/s Getz Pharma
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 00243/044/2022
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 00244/135/2010, 00243/135/2010, 00244/137/2010.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** ZOOKA 200mg Suspension **Reference product:** Cefiget DS 200mg/5ml, Batch No._____mfg.:_____, Exp._____manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, weight variation, uniformity of dosage unit and assay **CDP:** **At pH 1.2:** F2 = 80 **At pH 4.5:** F2 = 92 **At pH 7.2:** F2 = 74
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala, 34 KM, Ferozpur Road Lahore.		
API Lot No.	00243/044/2022		
Description of Pack (Container closure system)	White to off white powder after reconstitution formed, having orange flavour and slightly bitter taste.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	5WD200	5WD201	5WD202
Batch Size	6666 bottles	6666 bottles	6666 bottles
Manufacturing Date	05.2022	05.2022	05.2022
Date of Initiation	05.2022	05.2022	05.2022
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Copy of section approval letter of drug product manufacturer is required.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.
3.	3.2.P.2	Exactly same data is submitted as that of 100mg/5ml strength. Clarify and provide batch No, mfg date and exp date of reference product used. Pictorial evidence of the reference product used in pharmaceutical equivalence is required.
4.	3.2.P.8	Chromatograms submitted are not visible. Clear copies of chromatograms are required.
5.	3.2.P.8	Audit trail of HPLC is required.
6.	3.2.P.8	The chromatograms submitted are not readable. The chromatogram images are copy pasted on another page and stretched as an image. Clarify why images of chromatograms are edit. Further submit real chromatograms in the actual form as they are acquired by the system.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

305.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Onyx Pharmaceuticals 30-A, Industrial Estate Mansehra (DML No. 000440)**
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore. DML No. 000863.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26.02.2020 valid till 12.02.2022 issued by DRAP Lahore in favour of M/s Bio-Mark is provided. (Firm has applied for new GMP certificate)
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 6373 dated 06.03.2023
	Details of fee submitted	PKR 75,000/- Slip No. 6803447638 dated 09.02.2023
	The proposed proprietary name / brand name	**SONYX 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ondansetron (as HCl)…….8mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	Pharmaceutical form of applied drug	A film coated pink colour round biconvex tablet, in alu alu blister with leaflet pack in unit carton.
	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	Zofran Tablets 8 mg MHRA Approved.
	For generic drugs (me-too status)	Onden 8mg Tablet Reg. No. 055754 M/s Macter Karachi.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50, C62 & C-63 KSSIDC Industrial Estate, Doddaballapur, Bengaluru India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. AOND-18006
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 7DON0010417, 7DON0020417, 7DON0030517
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** SOSET 8mg tablet Batch No. 21C254 mfg 09.2021 **Reference product:** Onset 8mg Tablets, Batch No. 252. mfg.: 07.2019, Exp. 07.2024 manufactured by M/s Pharmedic Lahore. Pictorial evidence is submitted. **Tests done:** physical characteristics, Identification, Dissolution, Average weight, uniformity of dosage, Assay. **CDP:**

		At pH 1.2: F2 = not submitted **At pH 4.5:** F2 = more than 85% in 15 min **At pH 6.8:** F2 = more than 85% in 15 min
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Anugraha Chemicals, D-47, D-48, D-49, D-50 & C-62 KSSIDC, Industrial Estate Doddaballapur India.		
API Lot No.	AOND-18006		
Description of Pack (Container closure system)	A film coated pink colour round biconvex tablet, in alu alu blister with leaflet pack in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21C254	21D286	21J367
Batch Size	100,000 tablets	100,000 tablets	100,000 tablets
Manufacturing Date	09.2021	09.2021	09.2021
Date of Initiation	09.2021	09.2021	09.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. DCD/SPL-1/CR-1733/2021-22 dated 31.01.2022 valid till 30.01.2023 issued by Drug Control department Karnataka state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ondansetron hydrochloride dihydrate USP** Batch No.: AOND-18006 Mfg date: 09.2018 Quantity: 5Kg Invoice No.: FPL0225/18-19 Invoice date: 24.09.2018 Cleared by: AD I&E DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	1.5.2	The label applied is Ondansetron (as HCl), the innovator product uses Ondansetron as hydrochloride dihydrate. Clarify.

2.	3.2.P.2.2	The F2 factor calculations in CDP are not submitted.	
3.	3.2.P.8	Copies of executed BMR of stability batches are required.	

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

306.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi. (DML No. 000837)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205, Industrial Triangle, Kahuta road Islamabad. DML No. 000417
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 3-16/2018-Addl. Dir (QA&LT-I)-1 dated 04.01.2022 valid till 02.01.2024 issued by DRAP Islamabad in favour of M/s Global Pharmaceuticals is provided.
	Evidence of approval of manufacturing facility	Copy of GMP certificate mentioning Capsule general and softgel capsule general sections is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7171 dated 13.03.2023
	Details of fee submitted	PKR 75,000/- Slip No. 56029396320 dated
	The proposed proprietary name / brand name	**TAMCURE-D Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Dutasteride (as softgel capsule) ….0.5mg Tamsulosin HCl (as 0.2% modified release pellets)..... 0.4mg
	Pharmacotherapeutic Group of (API)	DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC Code: G04CA52
	Pharmaceutical form of applied drug	Off white spherical pellets filled in empty HDSC with off white softgel capsule containing clear colourless translucent oily solution.
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DUTASTERIDE / TAMSULOSIN HYDROCHLORIDE 0.5MG / 0.4MG HARD CAPSULES MHRA Approved.
	For generic drugs (me-too status)	Max flow D Capsule Reg. No. 091571 M/s CCL Pharmaceuticals.

	Name and address of API manufacturer.	**Tamsulosin HCl 0.2% SR pellets** M/s Vision Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. **Dutasteride** M/s Stermone Chemicals (Pvt.) ltd. Survey No 36, Golana Road, PaldiSokhada, Tal-Khambhat, Dist. Anand, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Tamsulosin HCl 0.2% SR pellets** TMS347, TMS351 **Dutasteride** SCPL/DS/010/2021, SCPL/DS/016/2021.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (18 months of Dutasteride) **Tamsulosin HCl 0.2% SR pellets** TMS205T, TMS208, TMS 206 **Dutasteride** SCPL/DS/001/2021, SCPL/DS/002/2021, SCPL/DS/003/2021.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Tamsol D Capsule, Batch No. 22C135 **Reference product:** Duodart Capsule, Batch No. -4944285A. mfg.:03.2022, Exp. 09.2023manufactured by M/s GSK Pakistan Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, average weight, Assay and dissolution.

		CDP: **At pH 1.2:** F2 = 98.96 & 77.03 **At pH 4.5:** F2 = 82.1618 **At pH 7.2:** F2 = 89.59
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Tamsulosin HCl 0.2% SR pellets** M/s Vision Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. **Dutasteride** M/s Stermone Chemicals (Pvt.) ltd. Survey No 36, Golana Road, PaldiSokhada, Tal-Khambhat, Dist. Anand, Gujrat India.		
API Lot No.	Dutasteride SCPL/DS/010/2021 Tamsulosin HCl SR pellets TMS347, TMS351		
Description of Pack (Container closure system)	Off white spherical pellets filled in empty HDSC with off white softgel capsule containing clear colourless translucent oily solution.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22C135	22C136	-
Batch Size	200,000 capsules	75000 capsules	-
Manufacturing Date	03.2022	03.2022	-
Date of Initiation	06.03.2022	18.03.2022	-
No. of Batches	2		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Tamsulosin HCl 0.2% SR pellets** Copy of GMP certificate No. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22.08.2022 valid till 13.06.2024 issued by DRAP Islamabad is submitted. **Dutasteride** Copy of GMP certificate No. S-GMP&GLP/21052579 valid till 31.05.2023 issued by food and drug control administration Gujrat India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Tamsulosin HCl 0.2% SR pellets** Local purchase from M/s Vision **Dutasteride** Batch No. SCPL/DS/010/2021 Mfg: 04.2021 Exp: 03.2025 Invoice No.:EX/RU/002/21-22 Dated: 12.04.2021 Cleared by AD I7E DRAP Islamabad.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2	In CDP, F2 factor calculations for dutasteride at pH 4.5 and 6.8 are not provided.	The firm vide letter No. nil dated 15.12.2023 has submitted their reply. The firm has submitted F2 factor calculations as under; At pH 1.2 = 77.72 At pH 4.5 = 73.82 At pH 6.8 = 77.03

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application

307.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s UniMark Pharmaceuticals (Pvt.) Ltd. Plot No. 7-A, National Industrial Zone Rawat. (DML No. 000557)**
	Name, address of Manufacturing site.	M/s Swiss Pharmaceuticals(Pvt.) Ltd. A/159, S.I.T.E. Super Highway Karachi. DML No. 000557
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 52/2022-DRAP (K) dated 04.04.2022 valid till 17.03.2024 issued by DRAP Karachi in favour of M/s Swiss Pharma is provided.
	Evidence of approval of manufacturing facility	Not submitted. Copy of approval of layout plan letter is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7171 dated 13.03.2023
	Details of fee submitted	PKR 75,000/- Slip No. 796720264 dated 08.12.2022
	The proposed proprietary name / brand name	**VOMFRAN 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Ondansetron as Hydrochloridedihydrate..8mg

	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	Pharmaceutical form of applied drug	Clear, almost colourless solution, free from any visible particle filled in amber glass ampoule.
	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	Ondansetron 8mg/4ml Injection (ondansetron hydrochloride) - PL 04543/0508 MHRA Approved.
	For generic drugs (me-too status)	Zofran 8mg/4ml Injection Reg. No. 020669 M/s GSK Karachi.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, D-47, D-48, D-49, D-50 & C-62 KSSIDC, Industrial Estate Doddaballapur India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. AOND20003
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. AOND-17002, AOND-17003 AOND-17004.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** VOMFRAN 8mg/4ml Injection Batch No. 01 **Reference product:** Zofran 8mg Injection, Batch No. TA9B. mfg.:04.2020, Exp. 05.2023

		manufactured by M/s GSK Pakistan Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Anugraha Chemicals, D-47, D-48, D-49, D-50 & C-62 KSSIDC, Industrial Estate Doddaballapur India.		
API Lot No.	AOND20003		
Description of Pack (Container closure system)	Clear, almost colourless solution, free from any visible particle filled in amber glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	01	2	3
Batch Size	18410 ampoules	23463	22236 ampoules
Manufacturing Date	09.2020	11.2020	10.2021
Date of Initiation	10.09.2020	30.12.2020	29.10.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. DCD/SPL-1/CR-1733/2021-22 dated 31.01.2022 valid till 30.01.2023 issued by Drug Control department Karnataka state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ondensetron HCL Injection grade** Batch No. AOND20003 Mfg: 02.2020 Exp: 01.2025 Invoice No.: PCI/CI20/06002 Dated: 15.06.2020 Cleared by AD I&E DRAP Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Layout approval letter is provided. Section Approval letter is required.

2.	3.2.P.5	The specifications claimed for the drug product are USP specifications. As per USP monograph, for system suitability and verification of chromatographic system ondansetron related compound A is required to be used. The submitted method does not indicate system suitability as per USP monograph. Justify.	
Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.			

Case no. 03 Registration applications to be considered on Priority as per 257th meeting of Registration Board

The board in its 257th meeting decided that drugs for treatment of cancer, viral diseases, thalassemia, immunosuppressant, vaccine and sera, new molecules / formulations, blood factors and bags will be given priority consideration.

308.	**Name, address of Applicant / Importer**	M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi.
	Details of Drug Sale License of importer	**License No**: 235 **Address**: A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi. Address of Godown: NA **Validity**: 21.Dec 2027 **Status**: Drug License by Way of Whole Sale. **Technical Person:** Ms. Saher D/o Sikander.
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name, address of manufacturer(s)	**M/s Cipla Ltd.** S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2022/71) dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India**. Name and dosage form on the CoPP certificate mentioned is "PICICLIB 75 capsules" and name of the product license holder is M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned in list of importing countries on CoPP. **GMP:** Applicant has submitted copy of GMP certificate No. 789/MFG/WHO-GMP/DFDA/2022/886 dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India** in the name of M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial

		Estate, Verna, Goa, **India.** having its manufacturing site at same address. As per certificate, last inspection of the manufacturer was conducted on 25th & 26th April, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization. The letter specifies that product license holder i.e. M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India authorizes M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi to import below mentioned products for the territory of Pakistan. *PICICLIB 75mg Capsule* *PICICLIB 100mg Capsule* *PICICLIB 125mg Capsule* *Enzalutamide 40mg Capsule* *Nilotinib 150mg Capsules* *Nilotinib 150mg Capsules*
	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. 21293 dated 29-08-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 38927334 Dated: 10.04.2023
	The proposed proprietary name / brand name	**PICICLIB 75mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each capsule contains:** Palbociclib……75mg.
	Pharmaceutical form of applied drug	Hard gelatin capsules in HDPE containers.
	Pharmacotherapeutic Group of (API)	Cyclin-dependent kinase (CDK) inhibitors. ATC Code: L01EF01
	Reference to Finished product specifications	**Manufacturer's Specifications.**
	Proposed Pack size	21's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	IBRANCE 75mg, 100mg & 125mg Capsules USFDA Approved.
	For generic drugs (me-too status)	Ibrance 75mg Reg. No. 103786 M/s Pfizer Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s MSN Laboratories Pvt. Ltd. Sy. No. 50, Kardanur (Village) Patancheru (mandal) Sangareddy District Telangana, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (0000693819, 0000693821, 0001190410) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. ZP0020618, ZP0030618, ZP0040618
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (GJ20380)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Ibrance capsules 75mg Lot No. R93133 manufactured by Pfizer exp date: 08.2018, by performing following tests; Average weight, DT, Assay, water content, total degradation products, CDP at pH 1.2 only with Ibrance 75mg. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle with child resistant cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30℃ ± 2℃, 75% ± 5% for 24 months**. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. GJ80697, GJ80698, GJ80699.
	Therapeutic indications in USFDA.	IBRANCE is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-basedtherapy for their metastatic disease. This indication is approved under accelerated approval based on

		progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.
2.	3.2.P.2	For 75mg strength, CDP with Ibrance is done only at pH 1.2. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8.

Decision: The Registration board deferred the case for submittion of

1. **comparative dissolution profile (CDP) studies of the applied product with relevant strength of innovator/comparator product at pH 4.5 & 6.8 as CDP at only pH 1.2 with Ibrance 75mg has been performed.**
2. **The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.**

309.	**Name, address of Applicant / Importer**	M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi.
	Details of Drug Sale License of importer	**License No**: 235 **Address**: A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi. Address of Godown: NA **Validity**: 21.Dec 2027 **Status**: Drug License by Way of Whole Sale. **Technical Person:** Ms. Saher D/o Sikander.
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name, address of manufacturer(s)	**M/s Cipla Ltd.** S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2022/72) dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India**. Name and dosage form on the CoPP certificate mentioned is "PICICLIB 100 capsules" and name of the product license holder is M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned in list of importing countries on CoPP. **GMP:** Applicant has submitted copy of GMP certificate No. 789/MFG/WHO-GMP/DFDA/2022/886 dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India** in the name of M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial

		Estate, Verna, Goa, **India.** having its manufacturing site at same address. As per certificate, last inspection of the manufacturer was conducted on 25th & 26th April, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization. The letter specifies that product license holder i.e. M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India authorizes M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi to import below mentioned products for the territory of Pakistan. *PICICLIB 75mg Capsule* *PICICLIB 100mg Capsule* *PICICLIB 125mg Capsule* *Enzalutamide 40mg Capsule* *Nilotinib 150mg Capsules* *Nilotinib 150mg Capsules*
	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. 21294 dated 29-08-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 258771594917 Dated: 12.04.2023
	The proposed proprietary name / brand name	**PICICLIB 100mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each capsule contains:** Palbociclib……100mg.
	Pharmaceutical form of applied drug	Hard gelatin capsules in HDPE containers.
	Pharmacotherapeutic Group of (API)	Cyclin-dependent kinase (CDK) inhibitors. ATC Code: L01EF01
	Reference to Finished product specifications	**Manufacturer's Specifications.**
	Proposed Pack size	21's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	IBRANCE 75mg, 100mg & 125mg Capsules USFDA Approved.
	For generic drugs (me-too status)	Ibrance 100mg Reg. No. 103787 M/s Pfizer Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s MSN Laboratories Pvt. Ltd. Sy. No. 50, Kardanur (Village) Patancheru (mandal) Sangareddy District Telangana, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (0000693819, 0000693821, 0001190410) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. ZP0020618, ZP0030618, ZP0040618
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (GJ80653)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Ibrance capsules 100mg Lot No. R72228 manufactured by Pfizer exp date: 04.2018, by performing following tests; Average weight, DT, Assay, water content, total degradation products, CDP at pH 1.2 only with Ibrance 100mg. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle with child resistant cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30℃ ± 2℃, 75% ± 5% for 24 months**. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. GJ80674, GJ80675, GJ80676.
	Therapeutic indications in USFDA.	IBRANCE is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-basedtherapy for their metastatic disease. This indication is approved under accelerated approval based on

		progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.
2.	3.2.P.2	For 75mg strength, CDP with Ibrance is done only at pH 1.2. The firm has done in-vivo bioequivalence of 125mg strength product and then have done CDP of 75mg and 100mg strength against 125mg strength at pH 1.2, 4.5 & 6.8.

Decision: The Registration board deferred the case for submittion of

1. **comparative dissolution profile (CDP) studies of the applied product with relevant strength of innovator/comparator product at pH 4.5 & 6.8 as CDP at only pH 1.2 with Ibrance 100 mg has been performed**
2. **The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.**

310.	**Name, address of Applicant / Importer**	M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi.
	Details of Drug Sale License of importer	**License No**: 235 **Address**: A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi. Address of Godown: NA **Validity**: 21.Dec 2027 **Status**: Drug License by Way of Whole Sale. **Technical Person:** Ms. Saher D/o Sikander.
	Name and address of marketing authorization holder (abroad)	M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name, address of manufacturer(s)	**M/s Cipla Ltd.** S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. 789/MFG/WHO-GMP/DFDA/2022/73) dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India**. Name and dosage form on the CoPP certificate mentioned is "PICICLIB 125 capsules" and name of the product license holder is M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned in list of importing countries on CoPP. **GMP:** Applicant has submitted copy of GMP certificate No. 789/MFG/WHO-GMP/DFDA/2022/886 dated 22.06.2022 issued by **Directorate of Food & Drugs Administration, Govt of Goa, India** in the name of M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial

		Estate, Verna, Goa, **India.** having its manufacturing site at same address. As per certificate, last inspection of the manufacturer was conducted on 25th & 26th April, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Letter of Authorization. The letter specifies that product license holder i.e. M/s Cipla Ltd. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna, Goa, India authorizes M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st Floor Shafi Court, Civil Lines, Merewether Road, Karachi to import below mentioned products for the territory of Pakistan. *PICICLIB 75mg Capsule* *PICICLIB 100mg Capsule* *PICICLIB 125mg Capsule* *Enzalutamide 40mg Capsule* *Nilotinib 150mg Capsules* *Nilotinib 150mg Capsules*
	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. 21295 dated 29-08-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 2051718120 Dated: 12.04.2023
	The proposed proprietary name / brand name	**PICICLIB 125mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each capsule contains:** Palbociclib……125mg.
	Pharmaceutical form of applied drug	Hard gelatin capsules in HDPE containers.
	Pharmacotherapeutic Group of (API)	Cyclin-dependent kinase (CDK) inhibitors. ATC Code: L01EF01
	Reference to Finished product specifications	**Manufacturer's Specifications.**
	Proposed Pack size	21's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	IBRANCE 75mg, 100mg & 125mg Capsules USFDA Approved.
	For generic drugs (me-too status)	Ibrance 125mg Reg. No. 103788 M/s Pfizer Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s MSN Laboratories Pvt. Ltd. Sy. No. 50, Kardanur (Village) Patancheru (mandal) Sangareddy District Telangana, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (0000693819, 0000693821, 0001190410) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. ZP0020618, ZP0030618, ZP0040618
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (GJ80651, GJ80652, GJ80657)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Ibrance capsules 125mg Lot No. S95591, DF8414 & R64950 manufactured by Pfizer by performing following tests; Average weight, DT, Assay, water content, total degradation products, CDP at pH 1.2, 4.5 & 6.8. Results of test and reference product are comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle with child resistant cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30℃ ± 2℃, 75% ± 5% for 24 months**. Accelerated at 40±2℃/75±5%RH for 6 months. Batch No. GJ80668, GJ80671, GJ80672.
	Therapeutic indications in USFDA.	IBRANCE is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-basedtherapy for their metastatic disease. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for

		this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Letter of authorization submitted is a photocopy. Notarized copy of Letter of Authorization is required.

Decision: Deferred for the submission of

1. **Notarized letter of authorization.**
2. **The documents as required under the approved Guidance Document Regarding Application of Drug Product Specifications vide no. No.9-2/2022-PEC dated 18th December, 2023 for the claim of manufacturers specifications.**

Case no. 04 The Authority in its 165th meeting held on 20th July, 2023 approved the out of Que consideration of Form 5-F applications of the following molecules received till 31st December, 2023, keepingin view of their repeated shortage/nonavailability reports in the market and to ensure timely access of these drugs to public.

1. labetalol injection
2. Calcium gluconate injection
3. Digoxin injection
4. Propofol injection
5. Cholestyramine powder/sachet
6. Lithium Carbonate Tablet
7. Pilocarpine Eye Drops
8. Heparine Injection
9. Divalproex sodium Tablet and injction
10. Anti-D injection
11. Streptokinase injection
12. Octreotide acetate injection
13. Carbamazepine tablet
14. Penicillin-G Benzathine injection
15. Fucidic acid cream
16. Calcitonin injection

311.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) ltd. A-20, North western Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) ltd. A-20, North western Industrial Zone, Bin Qasim, Karachi. DML No. 000415
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 40/2021-DRAP (K) dated 09.09.2021 valid till 06.09.2023 issued by DRAP Karachi is submitted.
	Evidence of approval of manufacturing facility	Copy of section approval letter No. 2-3/94-Lic (Vol-III) dated 16.11.2022 is submitted. Sachet (General) Section approved.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 473 dated 17.10.2023
	Details of fee submitted	PKR 75,000/- Slip No. 989396153 dated 21.12.2022
	The proposed proprietary name / brand name	**SEIZUNIL Granules 50%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1gram of granules contain; Carbamazepine…..... 500mg
	Pharmacotherapeutic Group of (API)	Carboxamide derivatives ATC Code: N03AF01
	Pharmaceutical form of applied drug	Off-white to slight yellow free flowing granules for oral suspension
	Reference to Finished product specifications	**Innovator Specifications.**
	Proposed Pack size	10g, 20g, 50g, 100g.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tegretol Fine Granules 50%〉 100g [bottle] PMDA Japan Approved
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s ZHEJIANG JIUZHOU PHARMACEUTICAL CO., LTD 99 Waisha Road, Jiaojiang District, Taizhou City, Zhejiang Province, 318000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. 200100A220131
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. 141201305

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Seizunil 50% granules. **Reference product:** Tegretol 50% granules. Batch No. _____. mfg.:_____, Exp. _____ manufactured by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics before and after reconstitution, Identification, General tests for sodium, pH, Loss on Drying, Uniformity of dosage units, dissolution test, Assay. **CDP:** Not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s ZHEJIANG JIUZHOU PHARMACEUTICAL CO., LTD 99 Waisha Road, Jiaojiang District, Taizhou City, Zhejiang Province, China		
API Lot No.	200100A220131		
Description of Pack (Container closure system)	Off-white to slightly yellow free flowing granules.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	1	2	3
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	06.12.2021	08.12.2021	09.12.2021
Date of Initiation	14.12.2021	16.12.2021	17.12.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of license No. ZHE 20000292 dated 09.02.2021 valid till 29.06.2025 issued by Zhejiang FDA China is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Carbamazepine** Batch No. 200100A220131 Mfg: Exp: Invoice No.: Dated:

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

Remarks of Evaluator:

Sr. No.	Section	Observation
2.	-	As per submitted data it is perceived that the drug product applied is 50% granules of carbamazepine, which will be packed in bottles having fill weight 10g, 20g, 50g, 100g, which then will be used for preparation of oral suspension. How volume will be made up to adjust same strength in 10g, 20g, 50g and 100g packs? Please clarify how this product will be used by the patients and how dose will be adjusted?
3.	-	Copy of clearance certificate or AD attested invoice of drug substance is required.
4.	1.5.11 & 3.2.P.5	In artwork, the specifications are mentioned as USP Specifications, in 3.2.P part, the specifications mentioned are innovator specs. Please clarify. Further if end product is an oral suspension then why USP monograph is not followed?
5.	3.2.S.7	Stability studies data of only one batch is provided. Real time and accelerated stability data of 3 batches of drug substance is required.
6.	3.2.P.2	The batch number, manufacturing date and manufacturer of reference product (Tegretol granules) are not mentioned. Further pictorial evidence of reference product is required.
7.	3.2.P.5.1	Why dissolution test is not part of specifications? Justify.
8.	3.2.P.8	It is not clarified that what was pack size of the drug product that was placed on stability.
9.	3.2.P.8	Copies of executed BMRs are required.
10.	3.2.P.8	If the product is intended for preparation of oral suspension, then why in-use stability is not performed?

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Case no. 05 Deferred case

312.	**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 **Address**: M/s AMB HK Enterprises (Pvt.) Ltd. Address of Godown: 2nd Floor Plaza 60, Commercial Block-K, Phase-1 DHA, Lahore **Validity**: 08.05.2028 **Status**: License to sell Drugs as Distributor

		Technical Person: Bilal Tariq S/o Muhammad Tariq (CNIC 3460186373527)
	Name and address of marketing authorization holder (abroad)	M/s Nanjing Hencer Pharamceutical Co. Ltd. No. 18 Jichang Road, Lishui Economic & Technological Development Zone Nanjing City, Jiangsu Province, China.
	Name, address of manufacturer(s)	**M/s Nanjing Hencer Pharamceutical Co. Ltd**. No. 18 Jichang Road, Lishui Economic & Technological Development Zone Nanjing City, Jiangsu Province, China.
	Name of exporting country	People's Republic of China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. JS20210513) dated 09.09.2021 issued by **Jiangsu Drug Administration China.** Name and dosage form on the CoPP certificate mentioned is "Sevelamer Carbonate Tablets Film Coated Tablets 0.8g" and name of the product license holder is Nanjing Hencer Pharamceutical Co. Ltd. The certificate also confirms that the applied formulation is actually on the market in the exporting country. The name of importing country on CoPP is mentioned as Pakistan. **GMP:** Applicant has submitted copy of GMP certificate No. JS20190973 dated 02.01.2019 issued by CFDA Jiangsu China in the name of M/s Nanjing Hencer Pharamceutical Co. Ltd. No. 18 Jichang Road, Lishui Economic & Technological Development Zone Nanjing City, Jiangsu Province, China having its manufacturing site at same address. The certificate confirms that manufacturer complies with the requirements of Chinese GMP for pharmaceutical products.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of exclusive distribution agreement. The agreement specifies that product license holder i.e. M/s Nanjing Hencer Pharmaceutical Co. ltd. wishes to grant exclusive license to M/s. AMB HK Enterprises Pvt. Ltd register, market sell and distribute the product 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. No. 8238 dated 25-03-2022.

	Details of fee submitted	PKR 150,000/- vide slip No. 9301075133 Dated: 11-01-2022
	The proposed proprietary name / brand name	**SEVEBEST 800mg Tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** Sevelamer carbonate…..... 800mg
	Pharmaceutical form of applied drug	White film coated oblong shaped tablets
	Pharmacotherapeutic Group of (API)	Drugs for treatment of hyperkalemia and hyperphosphatemia ATC Code: V03AE02
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	30's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	SEVELAMER CARBONATE 800 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Neovel 800mg Tablet Reg. No. 096586 M/s Seraph Pharmaceutical Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Nanjing Hencer Pharmaceutical Co. Ltd. No. 18 Jichang Road, Lishui Economic & Technological Development Zone Nanjing City, Jiangsu Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (180602-Tq, 180603-Tq, 7W1797-Tq) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40 ^{o}C± 2°C 75% ±5% RH: 6 months 30 ^{o}C± 2°C 65% ±5% RH: 48 months Batch No. 180601, 180602, 180603
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Renvela batch No. 9W3530, 7W1797, 7W2712 and 7W2714 manufactured by_____ exp date:_____, by performing following tests; Appearance, identification, weight variation, disintegration, total titratable amines, LOD, limit of soluble oligomers, Limit of Allylamine, **Phosphorus binding rate**, microbial limit assay and elemental impurities.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	80mL HDPE white bottle with child resistant screw can and A1 induction seal and bottles are placed into small carton with a patient insert.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. The real time stability study data is conducted at 30 ºC± 2ºC 65% ±5% RH: for 48 months Accelerated stability studies are conducted at 40 ºC± 2ºC 75% ±5% RH: for 6 months 30 ºC± 2ºC 65% ±5% RH: In use stability for 10 days. Batch No. 191201, 191202, 191203
	Therapeutic indications in USFDA.	Renvela is a phosphate binder **Indications and Usage** Renvela (sevelamer carbonate) is indicated for the control of serum phosphorus in 3 patients with chronic kidney disease (CKD) on dialysis. The safety and efficacy of Renagel in CKD patients who are not on dialysis have not been studied.

Evaluation by PEC:

Sr. No.	Section	Observations
1.	-	Copy of DSL submitted is in name of M/s MED-X Pharmacy and it's to sell drugs in a Pharmacy. Copy of valid DSL of applicant is required.
2.	-	Notarized copy of distribution agreement is required.
3.	-	Copy of GMP certificate of drug substance manufacturer is required. (is drug substance manufacturer same as drug product manufacturer? The drug substance is not mentioned in GMP certificate of M/s Nanjing Hencer Pharmaceutical Co. Ltd.
4.	3.2.P.2	• Why CDP is not performed. • Manufacturer, manufacturing date and expiry date of Reference product (Renvela) is not mentioned.
5.	3.2.P.5	Why dissolution testing of drug product is not performed.

Decision of 331st meeting of the Board: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings.

Evaluation by PEC:

Sr. No.	Section	Observations	Reply of Firm
1.	-	Copy of DSL submitted is in name of M/s MED-X Pharmacy and it's to sell	The firm vide letter No. nil dated nil has submitted copy of valid

			drugs in a Pharmacy. Copy of valid DSL of applicant is required.	DSL vide No. 05-352-0058-104514D valid till 08.05.2028	
	2.	-	Notarized copy of distribution agreement is required.	Legalized Exclusive Distribution Agreement is submitted. Product listed is only Sevelamer Carbonate 800mg Tablet 30 tablets/bottle M/s Nanjing Hencer Pharmaceutical Co Ltd has exclusively authorized M/s AMB HK Enterprises (Pvt.) Ltd. for sale of only this product in territory of Pakistan.	
	3.	-	Copy of GMP certificate of drug substance manufacturer is required. (is drug substance manufacturer same as drug product manufacturer? The drug substance is not mentioned in GMP certificate of M/s Nanjing Hencer Pharmaceutical Co. Ltd.	The firm has stated that Drug substance manufacturer is same as drug product manufacturer. The firm has submitted copy of GMP Compliance Inspection Results wherein it is mentioned that M/s Nanjing Hencer Pharmaceuticals Co ltd was inspected from 07.08.2020 to 09.08.2020 for API Sevelamer Carbonate and it conforms to GMP requirements.	
	4.	3.2.P.2	• Why CDP is not performed. • Manufacturer, manufacturing date and expiry date of Reference product (Renvela) is not mentioned.	The firm has submitted a statement of Drug product manufacturer that is reproduced below; "We, Nanjing Hencer Pharmaceutical Co. ltd. Declare that the dissolution test are not applicable for sevelamer carbonate tablets for following reasons; First drug substance of sevelamer carbonate is highly cross linked polymer with large molecular weight, which could not be absorbed by human body. Phosphate in GI tract will be absorbed to decrease phosphorus absorption and reduce the serum phosphate concertation. Second, based on guidelines by USFDA for sevelamer carbonate, dissolution test method is not applicable. Please check annex 1 for details. In the conclusion, dissolution is not applicable for sevelamer carbonate tablets 800mg,	
	5.	3.2.P.5	Why dissolution testing of drug product is not performed.		

				therefore it is not necessary to conduct CDP." The manufacturer of RLD Renvela is submitted as M/s Genzyme Europe BV, batch Nos 7W1797 (mfg 07.2017, Exp. 06.2020), 7W2712 (mfg 09.2017, Exp. 08.2020) 7W2714 (mfg 09.2017, Exp. 08.2020) against which comparative studies are done.	
Decision: Approved as per policy of inspection of manufacturer abroad.					

313.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	DOMMED 10mg Tablet
	Composition	Each film coated tablet contains; Domeperidone maleate 12.72 mg eq to domeperidone…..10mg
	Diary No. Date of R & I & fee	Dy. No. 17038 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786693 dated 06-03-2019, endorsed on 06.03.2019
	Pharmacological Group	Propulsives ATC code: A03FA03
	Type of Form	Form 5.
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	as per SRO.
	Approval status of product in Reference Regulatory Authorities	DOMPERIDONE ARROW 10 mg film-coated tablet ANSM France approved Domperidone 10 mg Tablets (uncoated) Each tablet contains 12.72 mg of Domperidone maleate equivalent to 10 mg Domperidone MhRA Approved.
	Me-too status	Motilium Tablet 10mg (Domeperidone HCl 10mg) Reg No. 006526 M/s Aspin Pharma (Pvt.) ltd. Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	The product approved by ANSM France does not mention maleate salt, whereas product approved in MHRA is uncoated. Further, me-too is approved as HCl salt. • Reference of finished product specifications is required.
	Decision of 327th meeting	**Deferred for following;** • **Reference of finished product specifications.** • **Revision of formulation as per innovator product along with submission of requisite fee.**

	Remarks of the Evaluator	The firm vide letter No. AD/HM/23-022 dated 21-08-2023 has stated that they have revised the label as under; Each film coated tablet contains; Domperidone as maleate…..10mg (BP Specifications) In EMC evidence of such formulation is available. (Domperidone of Milpharm limited UK)
	Decision: Approved with BP Specifications. Registration letter shall be issued after submission of fee of Rs. 7,500/- for preregistration variation/correction of product specifications, as per SRO 496(I)/2023 dated 17.04.2023	
314.	Name and address of manufacturer/ Applicant	M/s. City Pharmaceuticals, Plot 12-A, I-5, Sector 5, New Survey, No. 276, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Mybrol Tablet 450mg+35mg
	Composition	Each tablet contains: Paracetamol…450mg Orphenadrine Citrate…35mg
	Diary No. Date of R & I & fee	Dy. No.656, 30-04-2015 , Rs.20,000/- (29-04-2015)
	Pharmacological Group	Muscle relaxant with analgesic.
	Type of Form	Form 5.
	Finished product Specification	Reference of specs. not provided.
	Pack size & Demanded Price	100‘s: PVC/PVDC and Alu Blisters: As per PRC.
	Approval status of product in Reference Regulatory Authorities	Norgesic by M/s iNova Pharmaceuticals, Australia (TGA)
	Me-too status	Barfim of M/s Wisdom Pharmaceuticals, KPK (Reg.# 078572)
	GMP status	Last inspection conducted on 10-04-2017, — “Good”
	Remarks of the Evaluator	It has been found that application is still incomplete/deficient in respect of following deficiencies/shortcomings as mentioned: a) Reference of finished product specification in the light of decision taken by the Registration Board in its 267th meeting. b) Manufacturing outline of applied formulation is not specific to the product.
	Decision of 327th meeting	Deferred for the clarification of manufacturing outline as both direct compression and wet granulation are mentioned in the manufacturing of applied formulation.
	Remarks of the Evaluator	The firm vide letter No. nil dated 18.10.2023 has stated that they will manufacture their product by wet granulation method. Fee of Rs. 7500/- vide slip No. 858939513082 dated 27.10.2023 is submitted.
	Decision: Approved with innovator specifications.	
315.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Betosil Lotion 0.1%
	Composition	Each mL contains: Betamethasone Valerate equivalent to Betamethasone…….1mg.
	Diary No. Date of R & I & fee	(Duplicate Dossier) Dy. No. dated 28/05/2011 Rs. 8000/- (Photocopy fee challan not submitted) Differential fee (photocopy) of Rs. 12000/- submitted on 28/10/2015 Receipt of application has verified from R&I

	Pharmacological Group	Corticosteroids.
	Type of Form	Form 5.
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Emc approved formulation (One gram of cream contains 1 mg of betamethasone (0.1% w/w) as valerate)
	Me-too status	Betnovate (0.1%w/w) of M/s GSK, Pakistan
	GMP status	Last GMP inspection was conducted on 08-02-2021 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	Firm applied with different composition and availability in RRA could not be confirmed. Firm has separate dispensing booth for the steroidal product according to the panel inspection (inspection for renewal of DML) report dated 01.12.2020.
	Decision of 308th meeting	Deferred for Confirmation of Manufacturing facility for lotion preparations from Licensing Division.
	Remarks of the Evaluator	The vide letter No. nil dated nil has submitted a copy of inspection report dated 24.11.2022 (Renewal of DML inspection) wherein Topical Section (General) (Cream/ointment/lotions/gels etc) is mentioned. Similar product is approved in MHRA by name of betnovate lotion
	Decision: Approved.	
316.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	K-Zole Shampoo 2%.
	Composition	Each mL contains: Ketoconazole…….20mg
	Diary No. Date of R & I & fee	(Duplicate Dossier) dated 04/06/2011 Rs. 8000/- (Photocopy fee challan) Differential fee (photocopy) Rs. 12000/- submitted on 28/10/2015 (Date of STO stamp) Receipt of application verified from R&I.
	Pharmacological Group	Azole Antifungals.
	Type of Form	Form 5.
	Finished product Specification	Manufacturer's Specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA (Ketoconazole 2%w/w shampoo)
	Me-too status	Conaz of M/s Acto, Pakistan.
	GMP status	Last GMP inspection was conducted on 08-02-2021 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	□ Approved formulation in MHRA contain: *Each gram of shampoo contains 20 milligrams of Ketoconazole. Each 1 ml of shampoo contains 20.84 milligrams of Ketoconazole.* □ While the applied formulation is different i.e. Each ml contains 20mg of KETOCONAZOLE. □ Further firm claimed Manufacturer's specification while official monograph of applied formulation is present in BP.

	Decision of 308th meeting	Deferred for the followings: □ Revision of formulation as per the reference product i.e. Each gram of shampoo contains 20 milligrams of Ketoconazole. Each 1 ml of shampoo contains 20.84 milligrams of Ketoconazole along with submission of applicable fee, revise Form-5, master formula, manufacturing method. □ Confirmation of requisite manufacturing facility for medicated shampoo (external preparation section) from Licensing Division.
	Remarks of the Evaluator	The vide letter No. nil dated nil has submitted a copy of inspection report dated 24.11.2022 (Renewal of DML inspection) wherein Topical Section (General) (Cream/ointment/lotions/gels etc) is mentioned. The firm has not stated anything regarding label claim in their reply.
	Decision: The Board decided to defer the case and give last chance to the firm for submission of complete reply.	
317.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Peramin Lotion 5%.
	Composition	Each mL contains: Permethrin…….50mg.
	Diary No. Date of R & I & fee	(Duplicate Dossier) dated 18/10/2010 Rs.8000/- (Photocopy fee challan) Differential fee (photocopy) Rs.12000/- submitted on 26/03/2015. Receipt of application verified from R&I
	Pharmacological Group	Pyrethrins
	Type of Form	Form 5.
	Finished product Specification	Manufacturer's Specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Plaveo Lotion 50mg/ml of Hiranis Karachi
	GMP status	Last GMP inspection was conducted on 08-02-2021 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	
	Decision of 308th meeting	Deferred for Confirmation of Manufacturing facility for lotion preparations from Licensing Division.
	Remarks of the Evaluator	The vide letter No. nil dated nil has submitted a copy of inspection report dated 24.11.2022 (Renewal of DML inspection) wherein Topical Section (General) (Cream/ointment/lotions/gels etc) is mentioned.
	Decision: Defered for submissions of documents as required under the guidance document issued vide letter no. 9-2/2022-PEC dated 18.12.2023.	
318.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	SILON SHAMPOO 2.5%
	Composition	Each ml contains: Selenium Sulfide… 25mg
	Diary No. Date of R & I & fee	(Dy. No. 1195 dated 04-06-2011, Rs. 8,000/- dated 03-06-2011. (Fee challan copy dated 03-06-2011provided) Dy. No. dated, Differential fee Rs. /- vide challan No.

		dated. (Duplicate dossier, R & I verified vide Assist. Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020)
	Pharmacological Group	Other antifungals for topical use
	Type of Form	Form 5.
	Finished product Specification	USP Specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Selsun Lotion/Shampoo 2.5% Each 100 ml of suspension contains 2.5 g of Selenium Sulphide Ph. Eur.
	Me-too status	SELSUN SUSPENSION of M/s Abbott Pakistan, Karachi. Registration No. 000051
	GMP status	Last GMP inspection was conducted on 08-02-2021 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	Provide evidence of differential fee submission (DRAP R & I stamped cover letter copy of differential fee submission and differential fee challan). • USP monograph available as: Selenium Sulfide Topical Suspension is an aqueous, stabilized suspension of Selenium Sulfide. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of SeS2. It contains suitable buffering and dispersing agents. [NOTE—Where labeled for use as a shampoo, it contains a detergent. Where labeled for other uses, it may contain a detergent.] • Firm has provided letter No.F.1-67/2004-Lic dated 17- 06-2011 titled as "Grant of additional section – approval thereof" having "Topical preparation" section as evidence of availability of required manufacturing facility for the applied formulation. However, as per DML renewal report dated 01-12-2020, the firm has following sections: 1. Tablet Section (General) 2. Capsule-I Section (General) 3. Capsule-II Section (General) 4. Tablet Section (Psychotropic) 5. Cream/Ointment Section (General) 6. Dry suspension Section (General) 7. Sachet Section (General) 8. Sterile Ophthalmic (Section) 9. Capsule (Ceph) 10. Dry powder for suspension (Ceph).
	Decision of 308th meeting	Deferred for: • Evidence of approval of requisite manufacturing facilitiy by Licensig Division. • Evidence of differential fee submission (statistical officer signed/stamped cover letter, fee challan).
	Remarks of the Evaluator	The vide letter No. nil dated nil has submitted a copy of inspection report dated 24.11.2022 (Renewal of DML inspection) wherein Topical Section (General) (Cream/ointment/lotions/gels etc) is mentioned. Firm has also shared a copy of an old letter dated

		07.06.2011 wherein in Topical section is granted as an additional section. Firm has not submitted any evidence of differential fee.
	Decision: The Board decided to defer the case and give last chance to the firm for submission of complete reply.	
319.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Minodil Plus Topical Solution 5%
	Composition	Each ml contains: Minoxidil……50mg
	Diary No. Date of R & I & fee	Dy. No. 13685 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901266 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D11AX01 Other dermatologicals
	Type of Form	Form 5.
	Finished product Specification	USP Specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MINOXIDIL 5% CUTANEOUS SOLUTION MHRA Approved.
	Me-too status	Collin 5% Topical Solution Reg. No. 107326 M/s Saffron Pharma.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision of 308th meeting	Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion/Liquid section" from CLB.
	Remarks of the Evaluator	The vide letter No. nil dated nil has submitted a copy of inspection report dated 24.11.2022 (Renewal of DML inspection) wherein Topical Section (General) (Cream/ointment/lotions/gels etc) is mentioned.
	Decision: Approved.	
320.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Calinol-T Lotion 1%
	Composition	Each ml contains: Clindamycin Phosphate eq. to Clindamycin…....10mg
	Diary No. Date of R & I & fee	Dy. No. 13687 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901268 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D10AF01 Anti-infectives for treatment of acne
	Type of Form	Form 5.
	Finished product Specification	In house Specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	DALACIN T TOPICAL LOTION MHRA Approved.
	Me-too status	Lindagen 1% w/v Lotion Reg. No. 109303 M/s Biogen Pharma.
	GMP status	Report of 2018 is submitted.

	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision of 308th meeting	Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion/Liquid section" from CLB.
	Remarks of the Evaluator	The vide letter No. nil dated nil has submitted a copy of inspection report dated 24.11.2022 (Renewal of DML inspection) wherein Topical Section (General) (Cream/ointment/lotions/gels etc) is mentioned.
	Decision: Defered for submissions of documents as required under the guidance document issued vide letter no. 9-2/2022-PEC dated 18.12.2023..	

Agenda Evaluator PEC-X

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

a. New Cases

321.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Levaran Injection 100ml
	Composition	Each ml contains: Closantel..... 50mg Levamisole Hydrochloride as Levamisole base…..... 100mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 49 dated 10-07-2009 Rs.8,000/- dated 10-07-2009; Rs.12,000/- dated 10-09-2013 (**Duplicate fee challan attached**)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Closole Injection (100ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 062158)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Veterinary Liquid injection (General) section** granted vide letter No. F. 1-30/2001-Lic (M-212) dated 14-06-2008 • **Target species:** Cattle, sheep, camel, goat
	Decision: Approved. Fee shall be verified as per procedure adopted by the Registration Board in its 285th meeting. Moreover, firm shall submit 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.	
322.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Lactomin Gold granules
	Composition	Each gram contains: Vitamin A..... 0.8mg Vitamin D3…..... 0.16mg 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 DCP (Phosphorus)…..150mg Sodium chloride…..120mg Vitamin B6…..4mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 36 dated 10-07-2009 Rs.8,000/- dated 10-07-2009; Rs.12,000/- dated 10-09-2013 (**Duplicate fee challan attached**)
	Pharmacological Group	Multivitamins and minerals
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No.058842)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder (General) section** granted vide letter No. F. 1-30/2001-Lic dated 27-03-2007 • **Target species:** Cattle, horse, calves, foal, sheep, goat
	Decision: Deferred for confirmation of relevant testing facility required for applied formulation.	

b. Deferred Cases

323.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Broxine-10 Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 6872 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 327th meeting: 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.	
	Updated status: The firm has submitted the following:	

	Me-too/generic status: Ebrom-Lytic 10% Oral Liquid of M/s Vetec Laboratories, Rawalpindi. **Reg. No.** 099317	
	Decision: Approved.	
324.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-23 Oral Liquid
	Composition	Each ml contains: Florfenicol…230mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6866 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 327th meeting: 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.	
	Updated status: The firm has submitted the following: **Me-too/generic status:** Lorstrin-23 Oral Liquid of M/s Aamster Laboratories, Islamabad. **Reg. No.** 101425	
	Decision: Approved.	
325.	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-Streptocol Powder
	Composition	Each 1000Gm Powder Contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Bromhexine HCl…5gm Colistin Sulphate…450 MIU Streptomycin Sulphate…36gm
	Diary No. Date of R& I & fee	Dy.No 14420 dated 07-08-2019 Rs.20,000/- dated 06-08-2019
	Pharmacological Group	Antibiotic/ mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 1Kg: Decontrolled
	Me-too status	Streptodox Powder of M/s Attabak Pharma, Islamabad. **Could not be confirmed**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Oral Dry Powder section (Veterinary)** 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. • Provide conversion of Colistin sulphate from MIU to gm.
	Decision of 324th meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide conversion of Colistin sulphate from MIU to gm.	
	Updated status: The firm has revised the formulation as per following label claim: **Each gram contains:** **Tylosin as Tartrate…100mg** **Doxycycline HCl…200mg** **Bromhexine HCl…5mg** **Colistin Sulphate…0.45 MIU** **Streptomycin Sulphate…36mg** **Me-too/generic status:** Pulmodox-S Powder of M/s Attabak Pharmaceutical, Islamabad. **Reg. No.** 071069 • Conversion of Colistin sulphate from MIU to mg (19000 IU = 1mg) • The firm has submitted fee Rs. 30,000/- vide challan No. 9975143997 for pre-registration variation (revision of label claim and FPP specifications) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
	Decision: Approved with as per innovator's specifications and with following label claim. **Each gram contains:** **Tylosin as Tartrate…100mg** **Doxycycline HCl…200mg** **Bromhexine HCl…5mg** **Colistin Sulphate…0.45 MIU** **Streptomycin Sulphate…36mg** **Firm shall submit 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.**	
326.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Moxidek Injection
	Composition	Each vial contains: Moxidectin.....% w/v
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 63 dated 10-09-2013 Rs.20,000/- dated 10-09-2013 (**Duplicate fee challan attached**)
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Cydectin 1% Injectable **50ml** of M/s Rhone Poluene (Pvt) Ltd Lahore (Reg. No. 019034) **could not be confirmed in the applied fill volume**
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator [X]	**Veterinary Liquid injection (General) section** granted vide letter No. F. 1-30/2001-Lic (M-212) dated 14-06-2008 **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the **same fill volume as**

		applied alongwith registration number, brand name and name of firm.
	Decision of 323rd meeting: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the same fill volume as applied alongwith registration number, brand name and name of firm.	
	Updated status: The firm has revised the fill volume/ pack size from 100ml to **50ml** along with submission of fee Rs. 30,000/- vide challan No. 84013697905 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
	Decision: Approved with 50ml pack size. Firm shall submit 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. Moreover, fee shall be verified as per procedure adopted by the Registration Board in its 285th meeting.	
327.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Lostin-60 Injection 10ml
	Composition	Each ml contains: Colistin Sulphate…0.60 MIU
	Diary No. Date of R& I & fee	Dy.No 7658 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator X	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) withsame pack size alongwith registration number, brand name and name of firm. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision of 329th meeting: Deferred for following: • confirmation of relevant manufacturing facility from Licensing Division. • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size alongwith registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1-month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted following reply Dy. No. 21714 dated 04-09-2023 • **Liquid Injection Section Vial (Veterinary)** (New) confirmed vide letter No. F. 1-41/2006-Lic (Pt) dated 30-12-2020 • The applied product is registered in **50ml and 100ml** pack sizes/ fill volume	
	Decision: Approved. Firm shall submit 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.	
328.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Pentavetz Injection 50ml
	Composition	Each ml contains: Cyanocobalamine…0.5mg

		Sodium Selenite…1mg Adenosine Triphosphate Tetrasodium Dihydrate Salt…1mg Potassium Aspartate…10mg Magnesium Aspartate…15mg
	Diary No. Date of R& I & fee	Dy.No 861 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-stress
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Biosal Injection (50ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision of 329th meeting: Deferred for confirmation of relevant testing facility.	
	Updated status: The firm has submitted that all minerals in the applied product shall be tested through titration method and there is no need of Atomic Absorption Spectrophotometer. Analytical methods are also submitted.	
	Decision: Deferred for submission of analytical method validation studies for the proposed drug product test method..	
329.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Colimoxin Forte Injection 100ml
	Composition	Each ml Contains: Amoxicillin Eq. To Amoxicillin Trihydrate…140mg Colistin Sulphate…0.3 MIU
	Diary No. Date of R& I & fee	Dy.No 26585 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Moxil-C 50ml Injection **(50ml)** of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 085491) **Could not be confirmed in the applied fill volume/ pack size**
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Dry powder for injection (Penicillin) and liquid injection (Penicillin) Veterinary section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019 • Provided conversion of Colistin Sulphate from MIU to grams. (1MIU=50mg) **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with**same fill volume/ pack size as applied**, alongwith registration number, brand name and name of firm.

	Decision of 326th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same fill volume/ pack size as applied, alongwith registration number, brand name and name of firm.
	Updated status: Not registered with DRAP in the applied pack size. The firm had already been granted registration of Colipen Injection in 50 ml vide reg. No. 116981
	Decision: Approved. Firm shall submit 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.

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

a. New Cases

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:

1. Oral Powder Section-I Vet. (General)
2. Oral Powder Section-II Vet. (General)
3. Liquid Spray Section Vet. (General)
4. Liquid Section-I Vet. (General)
5. Liquid Section-II Vet. (General)
6. Liquid Injection Section Vet. (General)
7. Liquid Injectable Section Vet. (Steroid)
8. Liquid Injectable Penicillin (Veterinary)
9. Dry Powder Injectable Penicillin (Veterinary)
10. Bulk Powder Penicillin Section (Vet.)

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

Section	No. of Applied Products	No. of Molecule Applied
Oral Powder Section-II Vet. (General)	25	10
Liquid Section-I Vet. (General)	22	10

Oral Powder Section-II Vet. (General)
(25 Products/ 10 Molecules)

330.	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	Colizon 48% WSP
	Composition	Each gram contains: Colistin as Sulphate …… 48,00,000IU
	Diary No. Date of R& I & fee	Dy. No. 23346 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 39789858604)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Coli D/S Powder of M/s. Farm Aid Group (Reg. No. 057105)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry

		Shortcomings: Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved with following label claim: **Each gram contains:** **Colistin Sulphate …… 48,00,000IU** **Firm shall submit fee Rs. 30,000/- for revision of label claim in line reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
331.	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	Colizon 60% WSP
	Composition	Each gram contains: Colistin Sulphate …… 6,000,000IU
	Diary No. Date of R& I & fee	Dy. No. 23347 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 37951036338)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Neflorex 60 Water Soluble Powder of M/s. Breeze Pharma (Reg. No. 089855)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
332.	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	Lincozon 44 Pre-Mix
	Composition	Each gram contains: Lincomycin HCl 44mg
	Diary No. Date of R& I & fee	Dy. No. 23336 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 61461574797)
	Pharmacological Group	Lincosamide
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Lincobar-44 Powder of M/s. Baariq Pharmaceuticals (Reg. No. 088636)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
333.	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	Lincozon 11 Pre-Mix
	Composition	Each gram contains: Lincomycin HCl 11mg
	Diary No. Date of R& I & fee	Dy. No. 23334 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 771295368421)
	Pharmacological Group	Lincosamide
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Lincobar-11 Powder of M/s. Baariq Pharmaceuticals (Reg. No. 088637)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
334.	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	Lincozon Forte Pre-Mix
	Composition	Each gram contains: Lincomycin HCl 110mg
	Diary No. Date of R& I & fee	Dy. No. 23335 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 1614852662)
	Pharmacological Group	Lincosamide
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Lincobar-Forte Powder of M/s. Baariq Pharmaceuticals (Reg. No. 088635)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
335.	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	Neozon 50% WSP
	Composition	Each gram contains: Neomycin Sulphate 500mg
	Diary No. Date of R& I & fee	Dy. No. 23328 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 88294674)
	Pharmacological Group	Aminoglycoside, Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled

	Me-too status	Neolex Water Soluble Powder of M/s. Lexicon Pharmaceuticals Pvt. Ltd, Karachi (Reg. No. 049762)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
336.	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	Neozon 60% WSP
	Composition	Each gram contains: Neomycin (as Sulphate) ……. 600mg
	Diary No. Date of R& I & fee	Dy. No. 23329 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 37833944791)
	Pharmacological Group	Aminoglycoside, Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Mycin-60 Water Soluble Powder of M/s. Farm Aid Group, Haripur. (Reg. No. 088624)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved with following label claim: **Each gram contains:** **Neomycin Sulphate ……. 600mg** **Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
337.	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	Neozon 72% WSP
	Composition	Each gram contains: Neomycin Sulphate …… 720mg
	Diary No. Date of R& I & fee	Dy. No. 23330 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 274094197)
	Pharmacological Group	Aminoglycoside, Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Nemycin 72% Oral Powder of Grand Pharma (Reg. No. 103940)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:**

		Calves, goat, sheep, poultry
	Decision: Approved.	
338.	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	Neozon 100% WSP
	Composition	Each gram contains: Neomycin Sulphate 1000mg
	Diary No. Date of R& I & fee	Dy. No. 23331 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 5527145715)
	Pharmacological Group	Aminoglycoside, Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Neo-S 100 Powder of Evergreen Pharmaceutical (Reg. No. 088862)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
339.	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	Doxyzon 50% Powder
	Composition	Each gram contains: Doxycycline Hyclate …. 500mg
	Diary No. Date of R& I & fee	Dy. No. 23342 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 507909546)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Dox Plus 50% WSP of M/s. Bio Labs (Pvt.) Ltd. (Reg. No. 082498)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
340.	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	Doxyzon 98% Powder
	Composition	Each gram contains: Doxycycline Hyclate .....923.32mg (eq. to 800mg Doxycycline)
	Diary No. Date of R& I & fee	Dy. No. 23343 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 776027524)
	Pharmacological Group	Antibacterial

	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Doxyral 80% Water Soluble Powder For Oral Route of M/s. Orient Animal Health (Reg. No. 082504)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
341.	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	CT-Zon 20% WSP
	Composition	Each gram contains: Chlortetracycline HCl..... 200mg
	Diary No. Date of R& I & fee	Dy. No. 23349 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 26801718)
	Pharmacological Group	Tetracycline
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	CT More Water Soluble Powder by Moreno Iglisias Research Laboratories (Reg. No. 089851)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
342.	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	CT-Zon 25% WSP
	Composition	Each gram contains: Chlortetracycline as HCl 250mg
	Diary No. Date of R& I & fee	Dy. No. 23350 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 1582510281)
	Pharmacological Group	Tetracycline
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Meralin 250 W/S Powder by M/s. My Labs Pharma (Reg. No. 101462)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry **Shortcomings:**

		Firm shall submit fee Rs. 30,000/- for revision of label claim in line with pharmacopoeia as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved with following label claim: **Each gram contains:** **Chlortetracycline as HCl..... 250mg** **Firm shall submit fee Rs. 30,000/- for revision of label claim in line with pharmacopoeia as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
343.	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	Amantazon 10% WSP
	Composition	Each gram contains: **Amantadine HCl.....** 100mg
	Diary No. Date of R& I & fee	Dy. No. 23332 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 4416505712)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Metadine Powder of Farm Aid Group (Reg. No. 088040)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
344.	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	Amantazon 98% WSP
	Composition	Each gram contains: **Amantadine HCl.....** 980mg
	Diary No. Date of R& I & fee	Dy. No. 23333 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 144667034)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s. Leads Pharma (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
345.	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	Amprozon 20% WSP

	Composition	Each gram contains: Amprolium HCl..... 200mg
	Diary No. Date of R& I & fee	Dy. No. 23337 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 0061997178)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Ampromine Water Soluble Powder of M/s. Divine Pharmaceuticals (Reg. No. 085156)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, cattle, sheep, goats and other livestock species
	Decision: Approved.	
346.	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	Amprozon 50% WSP
	Composition	Each gram contains: Amprolium HCl..... 500mg
	Diary No. Date of R& I & fee	Dy. No. 23338 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 316867169200)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Amprol 500 Water Soluble Powder of M/s. Divine Pharmaceuticals (Reg. No. 084944)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, cattle, sheep, goats and other livestock species
	Decision: Approved.	
347.	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	Amprozon 60% WSP
	Composition	Each gram contains: Amprolium HCl..... 600mg
	Diary No. Date of R& I & fee	Dy. No. 23339 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 25986822080)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Amprol 600 WSP of M/s. Divine Pharmaceuticals (Reg. No. 084943)
	GMP status	New DML

	Remarks of the Evaluator	**Target species:** Poultry, cattle, sheep, goats and other livestock species
	Decision: Approved.	
348.	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	Amprozon 70% WSP
	Composition	Each gram contains: Amprolium HCl …… 700mg
	Diary No. Date of R& I & fee	Dy. No. 23340 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 8419542334)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Eter Amprolium 70 Oral Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 109854)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, cattle, sheep, goats and other livestock species
	Decision: Approved.	
349.	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	Amprozon 98% WSP
	Composition	Each gram contains: Amprolium HCl..... 980mg
	Diary No. Date of R& I & fee	Dy. No. 23341 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 034751644926)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Ampro-Forte Oral Powder of M/s. Breeze Pharma (Reg. No. 088630)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, cattle, sheep, goats and other livestock species
	Decision: Approved.	
350.	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	Tiamulon Powder
	Composition	Each gram contains: Tiamulin Hydrogen Fumarate eq. to Tiamulin base…125mg
	Diary No. Date of R& I & fee	Dy. No. 23344 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 667652530652)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	27.8gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm & 25000gm; Decontrolled
	Me-too status	SB Tiamulin Oral Powder of M/s. SB Pharma (Reg. No. 048219)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
351.	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	Tiamulon 45% Powder
	Composition	Each gram contains: Tiamulin Hydrogen Fumarate Eq. to Tiamulin Base … 450mg
	Diary No. Date of R& I & fee	Dy. No. 23345 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 44595438498)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	27.8gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm & 25000gm; Decontrolled
	Me-too status	Tiamubak 45% Oral Powder of M/s. Attabak Pharmaceutical (Reg. No. 048170)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
352.	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	Tricofon 96 WSP
	Composition	Each gram contains: Trichlorfon..... 960mg
	Diary No. Date of R& I & fee	Dy. No. 23351 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 73775309140)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Nawagan Powder by M/s. Attabak Pharmaceuticals (Reg. No. 053922)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock and pets
	Decision: Approved.	

353.	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	Tricofon 98 WSP
	Composition	Each gram contains: Trichlorfon..... 980mg
	Diary No. Date of R& I & fee	Dy. No. 23352 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 7528716355)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	TriGold Water Soluble Powder of M/s. Attabak Pharmaceuticals (Reg. No. 049700)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Livestock and pets
	Decision: Approved.	
354.	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	Anticoc WSP
	Composition	Each gram contains: Sulphaquinoxaline Sodium ... 200mg Sulphadimidine Sodium …… 82.5mg Diaveridine HCl..... 40mg Vitamin K3 ..... 2mg Vitamin A 28000IU
	Diary No. Date of R& I & fee	Dy. No. 23348 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 6224786249)
	Pharmacological Group	Anticoccidial, Antibiotic, Multivitamin
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Coxyda Oral Powder of M/s. Biogen Pharma (Reg. No. 058970
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Approved.	
Liquid Section-I Vet. (General) (22 Products/ 10 Molecules)		
355.	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	Enrozon-C 45 Liquid
	Composition	Each ml contains: Enrofloxacin ..... 250mg Colistin Sulphate 0.05MIU

	Diary No. Date of R& I & fee	Dy. No. 23278 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 21134209652)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Eflin- DA 25% Oral Liquid of M/s. Vetec Laboratories (Reg. No. 099306)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
356.	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	Enrozon-C 40 Liquid
	Composition	Each ml contains: Enrofloxacin .....200mg Colistin Sulphate 0.20MIU
	Diary No. Date of R& I & fee	Dy. No. 23277 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 4102581812)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Eflin- Dayz 20% Oral Liquid of Vetec Laboratories (Reg. No. 099305)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
357.	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	Enrozon-C 58 Liquid
	Composition	Each ml contains: Enrofloxacin .....100mg Colistin Sulphate 0.48MIU
	Diary No. Date of R& I & fee	Dy. No. 23274 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 4158684061)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Eflin-VL 10% Oral Liquid of M/s. Vetec Laboratories (Reg. No. 099309)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	

358.	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	Enrozon-C 23 Liquid
	Composition	Each ml contains: Enrofloxacin .....200mg Colistin Sulphate 30mg
	Diary No. Date of R& I & fee	Dy. No. 23276 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 92470739755)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Eflin-UA 20% Oral Liquid of M/s. Vetec Laboratories (Reg. No. 099307)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
359.	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	Enrozon-C 62 Liquid
	Composition	Each ml contains: Enrofloxacin .....100mg Colistin Sulphate 0.52MIU
	Diary No. Date of R& I & fee	Dy. No. 23275 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 9140500335)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Bioenrocolis Liquid of M/s. Elegance Pharma (Reg. No. 073916)
	GMP status	New DML
	Remarks of the Evaluator	
	Decision: Approved.	
360.	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	Mucozon 30% Liquid
	Composition	Each ml contains: Bromhexine HCl..... 10mg Menthol 20mg
	Diary No. Date of R& I & fee	Dy. No. 23267 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 1715164127)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications

	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	B-Menthol Liquid Farm Aid Group (Reg. No. 093825)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	
361.	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	Mucozon 60% Liquid
	Composition	Each ml contains: Bromhexine HCl..... 20mg Menthol 40mg
	Diary No. Date of R& I & fee	Dy. No. 23268 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 54876199392)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Broment Oral Solution of M/s. Baariq Pharmaceuticals (Reg. No. 094458)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	
362.	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	Mucozon 90% Liquid
	Composition	Each ml contains: Bromhexine HCl..... 50mg Menthol 40mg
	Diary No. Date of R& I & fee	Dy. No. 23269 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 5532237293)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Hexthol Liquid of M/s. Nawal Pharmaceuticals (Reg. No. 097984)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	
363.	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	Cinazon Liquid
	Composition	Each ml contains: Trimethoprim..... 25mg Sulphamethazine..... 50mg Sulphamethoxypyradizine … 75mg Enrofloxacin 75mg
	Diary No. Date of R& I & fee	Dy. No. 23270 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 6410822737)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Cinaprim Oral Suspension of M/s. Farm Aid Group (Reg. No. 099408)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, sheep and goat
	Decision: Approved.	
364.	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	Cinazon Extra Liquid
	Composition	Each ml contains: Trimethoprim..... 25mg Sulphamethazine..... 50mg Sulphamethoxypyradizine … 50mg Enrofloxacin 75mg
	Diary No. Date of R& I & fee	Dy. No. 23271 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 5132212746)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s. Bio Oxime (Reg. No. 074786)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Cattle, sheep and goat
	Decision: Approved.	
365.	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	Trimson Solution
	Composition	Each ml contains: Trimethoprim…80mg Sulphadiazine…400mg

	Diary No. Date of R& I & fee	Dy. No. 23265 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 8414551194)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Timobar Suspension of M/s. Baariq Pharmaceuticals (Reg. No. 079817)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, large animals
	Decision: Approved.	
366.	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	Tilmizon Liquid
	Composition	Each ml contains: Tilmicosin Phosphate … 250mg
	Diary No. Date of R& I & fee	Dy. No. 23266 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 72169055327)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Motil Liquid of M/s. Breeze Pharma (Reg. No. 075671)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry, cattle
	Decision: Approved.	
367.	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	Flox 28% Liquid
	Composition	Each ml contains: Florfenicol .....230mg Colistin Sulphate 0.5MIU
	Diary No. Date of R& I & fee	Dy. No. 23260 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 15165446)
	Pharmacological Group	Antibacterial , Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Coliflor Solution M/s. Selmore Pharma (Reg. No. 088091)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry

	Decision: Approved.	
368.	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	Flox 30% Liquid
	Composition	Each ml contains: Florfenicol .....250mg Colistin Sulphate 0.5MIU
	Diary No. Date of R& I & fee	Dy. No. 23261 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 30427290894)
	Pharmacological Group	Antibacterial , Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Flocol Liquid of M/s. D-Maarson Pharma (Reg. No. 074082)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
369.	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	Florzon 20% Liquid
	Composition	Each ml contains: Florfenicol 200mg
	Diary No. Date of R& I & fee	Dy. No. 23258 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 483740636)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Floricol Liquid M/s. Inshal Pharma (Reg. No. 073936)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
370.	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	Florzon 23% Liquid
	Composition	Each ml contains: Florfenicol 230mg
	Diary No. Date of R& I & fee	Dy. No. 23259 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 2933825600)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications

	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Baflor-23 Oral Solution M/s. Baariq Pharmaceuticals (Reg. No. 071096)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	
371.	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	Enrofine Oral Liquid
	Composition	Each ml contains: Enrofloxacin.....100mg Aminophylline..... 100mg Guaifenesin..... 40mg
	Diary No. Date of R& I & fee	Dy. No. 23272 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 0750517864)
	Pharmacological Group	Antibiotic, Bronchodilator, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Ensol- AG Oral Liquid of M/s. Biogen Pharma (Reg. No. 049720)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	
372.	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	Enrofine Forte Oral Liquid
	Composition	Each ml contains: Enrofloxacin.....100mg Aminophylline..... 40mg Guaifenesin..... 100mg
	Diary No. Date of R& I & fee	Dy. No. 23273 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 2582280098)
	Pharmacological Group	Antibiotic, Bronchodilator, Expectorant
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Enrophylline Oral Solution of M/s. Baariq Pharma (Reg. No. 080730)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	

373.	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	Bromzon-10 Liquid
	Composition	Each ml contains: Bromhexine Hydrochloride … 10mg
	Diary No. Date of R& I & fee	Dy. No. 23262 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 8989032893)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Vet Brom 1% Oral Liquid of M/s. Kayans Pharmaceuticals, Rawalpindi (Reg. No. 113490)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	
374.	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	Bromzon-20 Liquid
	Composition	Each ml contains: Bromhexine Hydrochloride … 20mg
	Diary No. Date of R& I & fee	Dy. No. 23263 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 643829014780)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Avixin-M 2% Oral Liquid of M/s U.M. Enterprises, Karachi. (Reg. No. 099038)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	
375.	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	Bromzon-50 Liquid
	Composition	Each ml contains: Bromhexine Hydrochloride … 50mg
	Diary No. Date of R& I & fee	Dy. No. 23264 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 9080208678)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications

	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Bromotech Liquid of M/s. Biorific Pharma (Reg. No. 090669)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Dogs, cats, horse, cattle
	Decision: Approved.	
376.	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	Pefloxzon Liquid
	Composition	Each ml contains: Pefloxacin methanesulfonate 139.6mg eq. to Pefloxacin …… 100 mg
	Diary No. Date of R& I & fee	Dy. No. 23279 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 1142838037)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Peperoxin Solution of Hassan Brothers (Reg. No. 082807)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Poultry
	Decision: Approved.	

Case no. 03 Registration applications of local manufacturing-Deferred cases (Veterinary):

377.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Enersel Injection 50ml
	Composition	Each ml Contains: L-Arginine HCl ..1.42mg L-Cysteine HCl ..0.02mg Monosodium Glutamate. 0.08mg L-Histidine HCl.. 0.02mg L-Isoleucine HCl .. 0.525mg L-Leucine. .....0.6mg L-Lysine HCl...0.525mg DL-Methionine. 0.525mg L-Threonine..... 0.35mg L-Tryptophan. 0.175mg L-Phenylalnine. 0.35mg L-Valine. .....0.525mg Thiamine HCl .. 0.1mg Riboflavin. 0.05mg Pyridoxine HCl.. 0.1mg Nicotinamide. ..... 3mg Dextrose ..50mg Calcium Chloride. 2mg

		Potassium Chloride...2mg Magnesium Sulphate...2mg Sodium Acetate. 7.5mg D-Pantothenol ..0.1mg
	Diary No. Date of R& I & fee	Dy.No 703 dated 09-01-2023 Rs.30,000/- dated 06-12-2022
	Pharmacological Group	Vitamins, amino acids & mineral supplements
	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 pack size**
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	• **Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 329th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: Not registered with DRAP in the applied pack size. The firm had already been granted registration of Enersel Injection in 250 ml vide reg. No. 112275 **Target species:** Cattle, Horse, sheep, dog, poultry	
	Decision: Approved.	

Case no. 04 Registration applications of import cases

a. Deferred cases (Veterinary)

378.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 26418 Dated 07-10-2020
	Fee including differential fee	Rs : 1,00,000 Dated 07-10-2020
	Brand Name +Dosage Form + Strength	Bovicef 25mg/ml Injectable Suspension
	Composition	Each ml Contains: Cefquinome as Cefquinome Sulphate…25mg

	Finished Product Specification	Inhouse
	Pharmacological Group	Cephalosporin antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	50ml
	International availability	N/A
	Me-too status	Cefanil Injection (50ml) of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 081319)
	Detail of certificates attached	Originally legalized COPP No. (2014)150252297 dated 03/03/2020 certified by Bureau of Animal Husbandry & Veterinary of Shandong Province, China confirms the GMP status of the manufacturer as well as free sale status of the product in exporting country. **Copy of Authorization Letter dated** 11-12-2017 Validity: 3 years
	Remarks of the Evaluator [X]	**Shortcomings:** • The submitted photocopy of letter of Authorization (LOA) is **expired now, but valid upon submission,** Provide legalized valid original LOA • Provide both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • Confirmation of dedicated manufacturing facility.
	Decision of 326th meeting: Deferred for following • legalized valid original LOA • both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • Confirmation of dedicated manufacturing facility	
	Updated status: The firm has submitted the following: • Bovicef injection is stable below 25ºC comes under the condition for refrigerator (2-8ºC), the firm has submitted 06 month accelerated (25ºC ± 2ºC/ 60%RH ± 5%RH) and 24-month real time (2-8ºC) stability studies data of three batches. • Original legalized LOA dated 20-08-2022 from M/s Qilu Animal Health Products Co. Ltd. China valid for 03 years. • Statement from M/s Qilu Animal Health Products Co. Ltd. China that Cefquinome Sulfate Injectable Suspension (Bovicef) is manufactured in our company by means of **dedicated manufacturing facilities for β-lactam** veterinary medicinal products, which can comply with the requirements of current GMP for preventing cross-contamination with other products. **Shortcomings:** • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
	Decision: Deferred for clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
379.	Name and address of Applicant	M/s Chakwal Pharma International, OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore
	Detail of Drug Sale License	Address: OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore Validity: 13/11/2021 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/S. Alfasan, Netherland B.V. Kuipersweg 9, 3449 JA Woerden The Netherland

	Name and address of marketing authorization holder	M/S. Alfasan, Netherland B.V. Kuipersweg 9, 3449 JA Woerden The Netherland
	Name of exporting country	The Netherland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 28427 Dated 15-10-2021
	Fee including differential fee	Rs : 150,000 Dated 20-09-2021(Slip No. 173118218)
	Brand Name +Dosage Form + Strength	Multivitamins Solution for Injection
	Composition	Each ml contains: Vitamin A…15,000 IU Cholecalciferol…1000 IU Alfa-Tocoferol Acetate…20mg Thiamine HCl…10mg Riboflavin Sodium Phosphate…6.85mg Pyridoxine HCl…3mg Cyanocobalamine…50mcg Nicotinamide…35mg D-Panthenol…25mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Multivitamins
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Not applicable
	Me-too status	Could not be confirmed in the applied strength
	Detail of certificates attached	➢ **Scanned copy of embassy attested COPP** BD/2017/No. of Certificate 247610 dated 14-06-2017 certified by Medicines Evaluation Board Agency-Veterinary Medicinal Products Unit, Ministry of Economic Affairs, The Netherlands confirms the free sale status in exporting country as well as GMP status of the manufacturer **(Copy of COPP attached, original was submitted for its pack size 250 mL registered, reg. No. 103799 dossier submission date 17-11-2017.)** ➢ Photocopy of letter of exclusive sole distributor/ authorization dated: 05-05-2017
	Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already **submitted copy** is **expired now but valid upon submission.** • Provide legalized original valid CoPP since already **submitted copy** is **expired now but valid upon submission.** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 330th meeting: Deferred for following: • copy of valid DSL • legalized original valid CoPP • notarized original valid Letter of Authorization/ Sole agency certificate	

	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the following reply dated 19-09-2023 and 27-11-2023: • copy of DSL valid till **13-11-2023** • Original legalized exclusive sole distribution/ authorization dated 03-11-2023. • Original Legalized COPP BD/2021/No. of Certificate 256589 dated 04-11-2021 certified by Medicines Evaluation Board Agency- Veterinary Medicinal Products Unit, Ministry of Economic Affairs, The Netherlands confirms the free sale status in exporting country as well as GMP status of the manufacturer • RRA status: The applied product is **approved in Netherlands** **Shortcomings:** • copy of valid DSL	
	Decision: Approved subject to inspection of the manufacturer abroad. The firm shall submit copy of valid DSL before issuance of registration letter.	
380.	Name and address of Applicant	M/s ZS Biotech, **Head office address**: 50-C, Madina Block, Awan Town, Multan Road, Lahore, Pakistan. **Warehouse address:** 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore.
	Detail of Drug Sale License	Name: M/s ZS Biotech Address: House No. 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore. **Validity: 20-01-2024.** Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Farmabase Saude Animal Ltda., Av. Emilio Marconato, n 1000-Jaguariuna, Brazil
	Name and address of marketing authorization holder	M/s Farmabase Saude Animal Ltda., Av. Emilio Marconato, n 1000- Jaguariuna, Brazil
	Name of exporting country	Brazil
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17500 Dated 23-06-2021
	Fee including differential fee	Rs : 1,50,000 Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Lincofarm TR Oral Powder
	Composition	Each gram contains: Lincomycin (hydrochloride)…440mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	200gram sachet
	International availability	N/A
	Me-too status	Could not be confirmed in the applied strength
	Detail of certificates attached	• Photocopy of FSC dated 05-10-2020 issued by the Ministry of Agriculture, Livestock, and Food Supply Livestock confirms free sale status of the product in country of origin. • Scanned copy of GMP Certificate dated 18-01-2023 issued by Ministry of Agriculture life stock and supply, Brazil.

		• Copy of legalized distribution agreement made on 13-06-2018 between the applicant and product license holder is provided. Validity: 36 Months
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions **Shortcomings:** • Submit legalized original valid FSC, since the already submitted is scanned copy. • Submit legalized original valid GMP certificate. • Provide notarized original valid distribution agreement between product license holder and distributor, since already submitted photocopy is **expired now but valid upon submission.** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 330th meeting: Deferred for following: • legalized original valid FSC • legalized original valid GMP certificate. • valid notarized original letter of authorization (LOA)/ distribution agreement • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the following reply dated 05-10-2023: • Scanned copies of legalized valid FSC, GMP and letter of clarification regarding distribution agreement. • The firm has applied for Each gram contains: Lincomycin (hydrochloride)…440mg Whereas the reference formulation is **Each gram contains:** **Lincomycin hydrochloride…440mg**	
	Decision: Approved subject to compliance to current import policy for finished drugs with following label claim, **Each gram contains:** **Lincomycin hydrochloride…440mg** **Firm shall submit the following before issuance of registration letter:** • **Fee Rs. 150,000/- for correction in formulation (label claim) in line with reference product and finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **legalized original valid FSC** • **legalized original valid GMP certificate** • **valid notarized original letter of authorization (LOA)/ distribution agreement**	
381.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Guangzhou Haicheng Pharmaceutical Co., Ltd. 311-312 A Yangming Nongzi Market, No.180-1 Tianyuan Road, Tianhe Area, Ghuangzhou China

	Name and address of marketing authorization holder	M/s Guangzhou Haicheng Pharmaceutical Co., Ltd. 311-312 A Yangming Nongzi Market, No.180-1 Tianyuan Road, Tianhe Area, Ghuangzhou China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 27955 Dated 11-10-2021
	Fee including differential fee	Rs : 1,50,000 Dated 05-10-2021 (slip No. 6505525117)
	Brand Name +Dosage Form + Strength	Halofuginone Hydrobromide 0.6% Powder
	Composition	Each gram Contains: Halofuginone Hydrobromide…6mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anticoccidial
	Shelf life	02 Years
	Demanded Price	N/A
	Pack size	Not demanded
	International availability	N/A
	Me-too status	Could not be confirmed
	Detail of certificates attached	• Original Legalized FSC dated 21-02-2021 issued by the Guangdong institute for Veterinary drug and feedstuffs inspection of Peoples Republic of China confirms Free sale status of applied product in country of origin. • Original Legalized GMP certificate dated 05-09-2020 issued by the Ministry of Agriculture Peoples Republic of China confirms GMP status of the manufacturer • Original Legalized LOA dated 12-03-2021 Validity: 1 year
	Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Notarized original sole agency/distribution agreement between PLH and Applicant since the already submitted is **expired now but valid upon submission.** • In the finished product label the Urdu version of the following namely; (i) Name of drug is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 330th meeting: Deferred for following: • valid notarized copy of letter of authorization (LOA)/ distribution agreement • label in accordance with The Drugs (Labelling and Packing) Rules, 1986 • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.	
	Updated status: The firm has submitted the following reply dated 01-11-2023: • Legalized original letter of authorization (LOA)/ distribution agreement dated 21-09-2023 valid for 5 years. • label in accordance with The Drugs (Labelling and Packing) Rules, 1986	

	• RRA status: Stenorol (Halofuginone Hydrobromide 0.6% Powder) in National office of Animal Health, UK (NAOH) compendium as **Specified Feed additive** **Shortcomings:** • Generic / RRA approval status of the applied product	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
382.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: 14 April, 2020. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company, Lot D1-D4, Dong Tho Industrial Complex, Yen Phong District, Bac Ninh Province, Vietnam
	Name and address of marketing authorization holder	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company, Lot D1-D4, Dong Tho Industrial Complex, Yen Phong District, Bac Ninh Province, Vietnam
	Name of exporting country	The Socialist Republic of Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12409 Dated 18-07-2019
	Fee including differential fee	Rs : 1,00,000 Dated 18-07-2019
	Brand Name +Dosage Form + Strength	Amoxi 50 S Powder
	Composition	Each 100g contains: Amoxicillin Trihydrate…50g
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	20gm, 50gm, 100gm
	International availability	N/A
	Me-too status	Not provided
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 351/2019/QLT-CFS issued by Ministry of Agriculture and Rural development department of Animal Health 15/78 GiaiPhong Street- DongDa- HaNoi- Vietnam Date of issuance: 03-05-2019 ➢ Original legalized GMP certificate No. 07/17/GCN-GMP issued on 06-06-2016 and valid for 5 years. (**scope of submitted GMP certificate does not cover beta lactam production line.)** ➢ Letter of Authorization/Sole Agency Certificate is not provided.
	Remarks of the Evaluator [X]	• Letter of Authorization (LOA) is not provied**,** Provide legalized valid original LOA. • Scope of submitted GMP certificate does not cover production lines of beta lactam oral powder,

		provide legalized original valid relevant GMP certificate. • Amoxicillin Trihydrate …50gm/100gm is mentioned in label claim on form-5A and FSC, while the referred generic product contains Amoxicillin as Trihydrate 50gm/100gm. Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm; or revise label claim in line with reference product and submit full fee of registration for revision of label claim/ master formula. • Provide valid copy of DSL • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. ➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.
	Decision of 322nd meeting: Deferred for following: • Original legalized valid Letter of Authorization (LOA) • Legalized original valid relevant GMP certificate with scope covering beta lactam production line. • Valid copy of DSL • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: • copy of DSL valid till 07-11-2027 • Original legalized Letter of Authorization (LOA) dated 01-06-2019 for the applied product. • Copy of legalized GMP certificate No. 23/22/GCN-GMP dated 25-07-2022 with scope covering beta lactam production line, valid for 5 years. • **Metoo status:** Rymox-50 Water Soluble Powder of M/s Zumars Pharma Fty (Pvt) Ltd., Karachi. (Reg. No. 069665) **Shortcomings:** • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
	Decision: Deferred for clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
383.	Name and address of Applicant	M/s Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Laboratories SYVA S.A.U

		Avda. Portugal, s/n, Parque technologico de Leon, Parcelas 15-16, Leon 24009 Leon Spain
	Name and address of marketing authorization holder	M/s Laboratories SYVA S.A.U Avda. Parroco Pablo Diez, 49-57 (24010) Leon Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24716 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No. 68437616724)
	Brand Name +Dosage Form + Strength	Dexabiopen Suspension for Injection
	Composition	Each ml contains: Benzyl Penicillin (Procaine)…200mg Dihydrostreptomycin (sulfate)…200mg **Dexamethasone**…0.5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial and corticosteroid
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Scanned copy of CoPP dated 17-12-2020 issued by Spanish agency of Medicines and Medical Devices, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Scanned copy of declaration dated 09-02-2021 of sole and exclusive distribution; valid for 5 years
	Remarks of the Evaluator [x]	Provided only **12 months long term** stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is scanned copy. • Provide legalized original valid CoPP since already submitted is scanned copy. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions. • Confirmation of **dedicated manufacturing facility** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 100ml and 250ml 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 and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registrationnumber, brand name and name of firm.
	Decision of 330th meeting: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Updated status: The firm has submitted the following: • legalized original valid CoPP No. 3170003050117 dated 17-12-2020 issued by the Spanish agency of Medicines and Medical Devices, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer	

	• copy of DSL valid till **14-10-2024** • Provided 06 months accelerated and 24 months' real time stability studies data as per zone IV-A conditions. • Demanded pack size: **100ml** **Shortcomings:** • Confirmation of dedicated manufacturing facility • original valid Letter of Authorization/ Sole agency certificate since the already submitted is scanned copy • Already referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and with submission of the following: • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise** • **original valid Letter of Authorization/ Sole agency certificate**	
384.	Name and address of Applicant	M/s Schiwo Pakistan, 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Schiwo Pakistan Address: 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan Date of validity: 26-08-2023. Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name and address of marketing authorization holder	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33649 Dated 17-12-2020
	Fee including differential fee	Rs : 1,00,000 Dated 17-12-2020
	Brand Name +Dosage Form + Strength	Asi-Amox Max
	Composition	Each 1000g Contains: Amoxicillin Trihydrate…500g
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	100gm, 1Kg
	International availability	N/A
	Me-too status	Amoxicilina 500 Karizoo of M/s Unicare Enterprises, Faisalabad. (Reg. No. 081302)
	Detail of certificates attached	Originally legalized FSC No. 1082/2019/QLT-CFS dated **26-09-2019** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms the free sale status of the product in exporting country. Validity: 2 years

		Scanned copy of GMP certificate dated **23-10-2017**certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms GMP status for production lines of Beta- lactam in the form of powder for oral use Scanned copy of Authorization Letter dated **14-06-2018**
	Remarks of the Evaluator [X]	➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-B conditions. **Shortcomings:** • The submitted Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Provide legalized valid original letter of Authorization (LOA) since already submitted is scanned copy.
	Decision of 326th meeting: Deferred for following: • Confirmation of dedicated manufacturing facility • legalized valid original FSC. • legalized valid original GMP certificate. • legalized valid original letter of Authorization (LOA)	
	Updated status: The firm has submitted the following • legalized original FSC No. 813/2023/QLT-CFS dated 18-07-2023 • legalized original GMP certificate Scanned copy of GMP certificate dated **27-06-2022** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms GMP status for production lines of Beta- lactam in the form of powder for oral use valid for two years. • Scanned copy of legalized original distribution agreement valid till 31-12-2030 **Shortcomings:** • Confirmation of dedicated manufacturing facility	
	Decision of 331st meeting: Deferred for confirmation of dedicated facility for the production of penicillin products.	
	Updated status: The firm has submitted the following • legalized original FSC No. 813/2023/QLT-CFS dated 18-07-2023 • Originally legalized COPP No. 158/23/QLT-CPP dated **31-05-2023** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms GMP status and free sale status of the product in exporting country, Validity: 2 years • original legalized LOA dated **14-06-2018**	
	Shortcomings: • Confirmation of dedicated manufacturing facility • original valid Letter of Authorization/ Sole agency certificate since the already submitted is expired now but valid upon submission.	
	Decision: Deferred for following: • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise** • **original valid notarized Letter of Authorization/ Sole agency certificate**	
385.	Name and address of Applicant	M/s Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi,

		Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zoopan-Produtos Pecuarios S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name and address of marketing authorization holder	M/s Zoopan-Produtos Pecuarios S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name of exporting country	Portugal
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24712 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No.0859549907)
	Brand Name +Dosage Form + Strength	Micoresp Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…100mg Doxycycline Hyclate…100mg Bromhexine Chlorhydrate…3.50mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial/ Expectorant, mucolytic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100gm, 500gm and 1000gm
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ **Unattested photocopy** of CoPP No. 208/CMVPT/2018 certified by The General Directorate of Food and Veterinary confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Photocopy of declaration **(not legalized)** dated 10-08-2021 of sole and exclusive distribution; valid for 5 years
	Remarks of the Evaluator [x]	The firm **has not provided** stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy not even legalized. • Provide legalized original valid CoPP since already submitted is unattested copy. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 330th meeting: Deferred for following: • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate. • legalized original valid CoPP • 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .	

	Updated status: The firm has submitted the following: • legalized original valid CoPP No. 617/CMVPT/2022 dated 04-10-2022 issued by Direção-Geral da Alimentação e Veterinária confirming the GMP and free sale status in Portugal. • original valid Letter of Authorization/ Sole agency certificate dated 10-08-2021 valid for 5 years • copy of DSL valid till **14-10-2024** • Provided 06 months accelerated and 24 months' real time stability studies data as per zone IV-A conditions. **Shortcomings:** • Generic /RRA approval status
	Decision: Deferred for evidence of approval status in RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Case no. 05 Registration applications of drugs for which stability study data is submitted

a. New cases

386.	Name and address of manufacturer / Applicant	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Cholimac 5mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…5mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16147 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets U.S (FDA) approved
	Me-too status	Obliva 5mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA	
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China
API Lot No.	JZ191101-1
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1 3, 6 (months)

	Real Time: 0, 3, 6 (months)		
Batch No.	CLT-PB-01	CLT-PB-02	CLT-PB-03
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	05-09-2020	05-09-2020	05-09-2020
No. of Batches	03		
Date of Submission	09-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Gencox 90mg Tablet, for which the inspection was conducted on 31-12-2020 and 11-01-2021, the report was presented in 312th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 12 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively. Batches:(201612001, 201612002, 201612003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. **Valid until May,05,2022**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not submitted**

7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** CLT-PB-01 / 900 tablets / 08-2020 CLT-PB-02 / 900 tablets / 08-2020 CLT-PB-03 / 900 tablets / 08-2020
11.	Record of comparative dissolution data (where applicable)	**Not Provided.** The firm has requested to exempt the study of CDP as Innovator or competitor product is not available in Pakistan.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted **except** COAs of all time points.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit documents for the procurement of API with approval from DRAP.
- Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- Submit record of comparative dissolution data
- Provide COAs of all time points of three stability batches for both accelerated and real time stability studies.

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

387.	Name and address of manufacturer / Applicant	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Cholimac 10mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…10mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16146 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10’s, 14’s, 20’s, 28’s, 30’s, As per SRO

	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets U.S (FDA) approved
	Me-too status	Obliva 10mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China		
API Lot No.	JZ191101-1		
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	CMT-PB-01	CMT-PB-02	CMT-PB-03
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	07-09-2020	07-09-2020	07-09-2020
No. of Batches	03		
Date of Submission	09-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Gencox 90mg Tablet, for which the inspection was conducted on 31-12-2020 and 11-01-2021, the report was presented in 312th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.

<table>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 12 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively.
Batches:(201612001, 201612002, 201612003)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. Valid until May,05,2022</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Not submitted</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>CMT-PB-01</td><td>900 tablets</td><td>08-2020</td></tr>
<tr><td>CMT-PB-02</td><td>900 tablets</td><td>08-2020</td></tr>
<tr><td>CMT-PB-03</td><td>900 tablets</td><td>08-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not Provided. The firm has requested to exempt the study of CDP as Innovator or competitor product is not available in Pakistan.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted except COAs of all time points.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Shortcomings:
Latest GMP inspection report conducted within period of 3 years.
Submit documents for the procurement of API with approval from DRAP.
Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
Submit record of comparative dissolution data
Provide COAs of all time points of three stability batches for both accelerated and real time stability studies.</td></tr>
</table>

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
388.	Name and address of manufacturer / Applicant	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Apixacol 5 mg Tablets
	Composition	Each Film Coated Tablet Contains: Apixaban…..... 5 mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16136 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Anticoagulant (selective direct factor Xa inhibitor)
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	ELIQUIS (apixaban) tablets USFDA approved
	Me-too status	NA
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	(Apixaban) M/s CHANGZHOU PHARMACEUTICAL FACTORY; Address: No.518, Laodong East Road, Changzhou, Jiangsu Province, PR China.		
API Lot No.	Apixaban: ZSAP200101		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	AZT-PB-01	AZT-PB-02	AZT-PB-03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	26-06-2020	26-06-2020	26-06-2020
No. of Batches	03		
Date of Submission	15-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 312th meeting dated 29,

<table>
<tr><td></td><td></td><td>January 2021, decided to approve registration of Gencox 90mgTablets(Etoricoxib) .
Inspection date: 31-12-2020 & 11-01-2021.
The report shows that:
• Finished Pharmaceutical Product stability testing was conducted on HPLC QC-EQ-003 for Gencox 90 mg tablets which were 21 CFR compliant for initial 6 months.
• Adequate monitoring and control were available for stability chamber.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copies of COAs (Batch# ZSAP200101) of API (Apixaban) from No.518, Laodong East Road, Changzhou, Jiangsu Province, and PR China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura -Pakistan are submitted.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturerare provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months.</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate ofAPI manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of DML no. 20160138 issued by Jiangsu Food and Drug Administration valid until 24-09-2025.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. CY119238B dated MAR.06, 2020 from exporter M/s Changzhou Pharmaceutical Factory, No.518, Laodong East Road, Changzhou, Jiangsu 213018, China, for import of 33 grams of Apixaban (Batch No. ZSAP200101) in name of M/s McOlson Research Labs. (Pvt) Ltd Lahore attested by AD (I&E) DRAP Lahore dated 11-03-2020.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>AZT-PB-01</td><td>1000 tablets</td><td>06-2020</td></tr>
<tr><td>AZT-PB-02</td><td>1000 tablets</td><td>06-2020</td></tr>
<tr><td>AZT-PB-03</td><td>1000 tablets</td><td>06-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed against Eliquis tablets (5mg) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) , Phosphate buffer (pH 6.8) & phosphate buffer 6.8 with 0.05% SLS</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like</td><td>Submitted</td></tr>
</table>

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [X]:

- Latest GMP inspection report conducted within period of 3 years.
- Justification shall be submitted for not including test of "Uniformity of Dosage Unit" by way of "content Uniformity" in finished drug product specifications.
- Justify the use of SLS in dissolution medium for performance of CDP studies of 5mg strength

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

389.	**Name and address of manufacturer / Applicant**	M/s McOlson Research Labs. (Pvt) Ltd. Plot No.2 26th km Lahore Shariqpur Road Sheikhpura
	Brand Name +Dosage Form + Strength	Apixacol 2.5 mg Tablets
	Composition	Each Film Coated Tablet Contains: Apixaban… .....2.5 mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 16137 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Anticoagulant (selective direct factor Xa inhibitor)
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	ELIQUIS (apixaban) tablets Initial U.S (FDA). Approval: 2012
	Me-too status	NA
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s CHANGZHOU PHARMACEUTICAL FACTORY; Address: No.518, Laodong East Road, Changzhou, Jiangsu Province, PR China.		
API Lot No.	Apixaban: ZSAP200101		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	AXT-PB-01	AXT-PB-02	AXT-PB-03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	06-2020	06-2020	06-2020

Date of Initiation	26-06-2020	26-06-2020	26-06-2020
No. of Batches	03		
Date of Submission	15-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 312th meeting dated 29, January 2021, decided to approve registration of Gencox 90mgTablets(Etoricoxib) . Inspection date: 31-12-2020 & 11-01-2021. The report shows that: • Finished Pharmaceutical Product stability testing was conducted on HPLC QC-EQ-003 for Gencox 90 mg tablets which were 21 CFR compliant for initial 6 months. • Adequate monitoring and control were available for stability chamber.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# ZSAP200101) of API (Apixaban) from No.518, Laodong East Road, Changzhou, Jiangsu Province, and PR China and M/s McOlson Laboratories (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura - Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML no. 20160138 issued by Jiangsu Food and Drug Administration valid until 24-09-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CY119238B dated MAR.06, 2020 from exporter M/s Changzhou Pharmaceutical Factory, No.518, Laodong East Road, Changzhou, Jiangsu 213018, China, for import of 33 grams of Apixaban (Batch No. ZSAP200101) in name of M/s McOlson Research Labs. (Pvt) Ltd Lahore attested by AD (I&E) DRAP Lahore dated 11-03-2020.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA

10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** AXT-PB-01 / 1000 tablets / 06-2020 AXT-PB-02 / 1000 tablets / 06-2020 AXT-PB-03 / 1000 tablets / 06-2020
11.	Record of comparative dissolution data (where applicable)	**Not Provided**
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [X]:

- Latest GMP inspection report conducted within period of 3 years.
- Submit Comparative dissolution profile for 2.5mg strength against innovator/reference product.
- Justification shall be submitted for not including test of "Uniformity of Dosage Unit" by way of "content Uniformity" in finished drug product specifications.

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

390.		
	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals Pvt Ltd., Plot No. 3 26 km Lahore-Shariqpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jencholic 5mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…5mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 15704 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets USFDA approved
	Me-too status	Obliva 5mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China

API Lot No.	JZ191101-1		
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JNC-PB-031001	JNC-PB-031002	JNC-PB-031003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	10-04-2020	10-04-2020	10-04-2020
No. of Batches	03		
Date of Submission	28-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Lansodex capsule 60mg and 30mg, Sofopas Tablet 400/90, for which the inspection was conducted on 10-12-2018, the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 12 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively. Batches:(201612001, 201612002, 201612003)

<table>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. Valid until May,05,2022</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. CY119050 dated 29-11-2019 from exporter M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China, for import of 92.5g of Obeticholic acid (Batch No. JZ191101-1) in name of M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura attested by AD (I&E) DRAP Lahore dated 12-12-2019.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>JNC-PB-031001</td><td>1000 tablets</td><td>04-2020</td></tr>
<tr><td>JNC-PB-031002</td><td>1000 tablets</td><td>04-2020</td></tr>
<tr><td>JNC-PB-031003</td><td>1000 tablets</td><td>04-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted
Comparative dissolution was performed against Abeticholic tablet (5mg) Reg. No. 109521 (Batch No. DY001) of M/s Dyson Research Laboratories in 0.1N HCl, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
</table>

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.

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

391.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals Pvt Ltd., Plot No. 3 26 km Lahore-Shariqpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jencholic 10mg Tablet
	Composition	Each film coated tablet contains: Obeticholic Acid…10mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 15705 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (**Duplicate fee challan attached**)
	Pharmacological Group	Farnesoid X receptor (FXR) agonist
	Type of Form	Form 5D
	Finished product Specifications	Innovator
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (obeticholic acid) tablets USFDA approved
	Me-too status	Obliva 10mg Tablet of M/s Hilton Pharma, Karachi.
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co;Ltd, No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China		
API Lot No.	JZ191101-1		
Description of Pack (Container closure system)	Alu- Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JNC-PB-032001	JNC-PB-032002	JNC-PB-032003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	10-04-2020	10-04-2020	10-04-2020
No. of Batches	03		

Date of Submission	28-06-2021	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Lansodex capsule 60mg and 30mg, Sofopas Tablet 400/90, for which the inspection was conducted on 10-12-2018, the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs of Obeticholic Acid (Batch# JZ191101-1) from M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China and M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura-Pakistan are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 12 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, & 0, 1, 2, 3 & 6 months respectively. Batches:(201612001, 201612002, 201612003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated May,06,2019 in the name of M/s Nantong Chanyoo Pharmatech Co;Ltd, Address: No.2 Tonghai Si Road ,Yangkou Chemical Industrial Park , Rudong Coastal Economic Development Zone ,Nantong , jiangsu Province 226407,P.R.China issued by Nantong Chemical Medical Industry Association. **Valid until May,05,2022**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CY119050 dated 29-11-2019 from exporter M/s Nantong Chanyoo Pharmatech Co; Ltd. No.2 Tonghai Si Road , Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407,P.R.China, for import of 92.5g of Obeticholic acid (Batch No. JZ191101-1) in name of M/s Jenner Pharmaceuticals (Pvt) Ltd;26-km,Lahore Sharikpur Road, District Sheikhpura

		attested by AD (I&E) DRAP Lahore dated 12-12-2019.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** JNC-PB-032001 / 1000 tablets / 04-2020 JNC-PB-032002 / 1000 tablets / 04-2020 JNC-PB-032003 / 1000 tablets / 04-2020
11.	Record of comparative dissolution data (where applicable)	Submitted Comparative dissolution was performed against Abeticholic tablet (10mg) Reg. No. 109522 (Batch No. DZ001) of M/s Dyson Research Laboratories in 0.1N HCl, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Submit valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.

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

392.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt.) Ltd. Plot 10 & 25 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Emaxy 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…..... 10 mg
	Diary No. Date of R& I & fee	Dy. No.36799 dated 06-11-2018, Fee Rs: 20,000/- dated 17-10-2018 vide deposit slip No.0742421.
	Pharmacological Group	Antidiabetic

	Type of Form	Form 5
	Finished product Specifications	In-House
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India.		
API Lot No.	08964005-EMP		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	054DS06	054DS05	054DS04
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020
No. of Batches	03		
Date of Submission	20-05-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	**Not provided**
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 08964005-EMP) of API from M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India and M/s Aspin Pharma (Pvt.) Ltd. Karachi are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A conditions. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 60 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(EM-001, EM-002, EM-003)

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/22033183 in the name of M/s Century Pharmaceuticals Limited, Panchmahal, India issued by Food and Drug Control Administration, Gujrat state. valid till 10-03-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CPLEXP1800165 dated 10-12-2018 from exporter M/s Century Pharmaceuticals Limited, India, for import of 1.5Kg of Empagliflozin (Batch No. 08964005-EMP) in name of M/s OBS Pakistan (Pvt) Ltd, Karachi attested by AD (I&E) DRAP Karachi dated 11-01-2019. Moreover, the firm has also submitted approval letter dated 28-02-2019 for transfer of API for R&D activities from OBS Pakistan Pvt. Ltd., to Aspin Pharma Pvt. Ltd., issued by DRAP.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	**Not Submitted**
10.	Complete batch manufacturing record of three stability batches.	**Not submitted**
11.	Record of comparative dissolution data (where applicable)	**Not Submitted**
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Provide Drug-excipients compatibility studies.
- Provide complete batch manufacturing record of three stability batches.
- Provide record of comparative dissolution data.
- Provide both accelerated and real time stability data summary sheets and COAs of all time points of three stability batches.
- In dissolution test, justify 30 minutes sampling time whereas the acceptance limit of innovator product is Q should release in 15 minutes.

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

393.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt.) Ltd. Plot 10 & 25 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Emaxy 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…..... 25 mg
	Diary No. Date of R& I & fee	Dy. No.36800 dated 06-11-2018, Fee Rs: 20,000/- dated 06-11-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	In-House
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India.		
API Lot No.	08964005-EMP		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	062DS07	062DS06	062DS05
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020
No. of Batches	03		
Date of Submission	20-05-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	**Not provided**
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 08964005-EMP) of API from M/s Century Pharmaceuticals Limited, 103-106, GIDC, Halol, Dist. Panchmahal, India and M/s Aspin Pharma (Pvt.) Ltd. Karachi are submitted.

3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A conditions. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 60 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(EM-001, EM-002, EM-003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/22033183 in the name of M/s Century Pharmaceuticals Limited, Panchmahal, India issued by Food and Drug Control Administration, Gujrat state. valid till 10-03-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. CPLEXP1800165 dated 10-12-2018 from exporter M/s Century Pharmaceuticals Limited, India, for import of 1.5Kg of Empagliflozin (Batch No. 08964005-EMP) in name of M/s OBS Pakistan (Pvt) Ltd, Karachi attested by AD (I&E) DRAP Karachi dated 11-01-2019. Moreover, the firm has also submitted approval letter dated 28-02-2019 for transfer of API for R&D activities from OBS Pakistan Pvt. Ltd., to Aspin Pharma Pvt. Ltd., issued by DRAP.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	**Not Submitted**
10.	Complete batch manufacturing record of three stability batches.	**Not submitted**
11.	Record of comparative dissolution data (where applicable)	Provided Comparative dissolution was performed against Jardiance tablet (25mg) Batch No. 906030 in HCl pH (1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Provide Drug-excipients compatibility studies.
- Provide complete batch manufacturing record of three stability batches.
- Provide both accelerated and real time stability data summary sheets and COAs of all time points of three stability batches.
- In dissolution test, justify 30 minutes sampling time whereas the acceptance limit of innovator product is Q should release in 15 minutes.

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

394.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd., 9.5 Km, Sheikhupura Road, Lahore.
	Brand Name +Dosage Form + Strength	Glifzin 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy. No.41298 dated 07-12-2018; Fee Rs: 50,000/- dated 07-12-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	Packed in a unit carton in a box of 2 x 10's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	GMP certificate issued based upon inspection conducted in 14-04-2022
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxing City, Liaoning Province, China.		
API Lot No.	E-20190310-D01-E06-03		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	EMA_t T2-21	EMA_t T3-21	EMA_t T4-21
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021

<table>
<tr><td colspan="2">No. of Batches</td><td>03</td></tr>
<tr><td colspan="2">Date of Submission</td><td>26-10-2021</td></tr>
<tr><td colspan="3">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>Sr. No.</td><td>Documents to Be Provided</td><td>Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Not provided</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copies of COAs (Batch# E-20190310-D01-E06-03) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s Neutro Pharma (Pvt) Ltd., Lahore are submitted.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone II. Stability study is conducted at Real time conditions; 25˚C ± 2˚C / 60% ± 5%RH for 12 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12 & 0, 1, 2, 3 & 6 months respectively.
Batches:(20160606, 20161017,20161219)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by Liaoning Fuxin Management committee, Fluoride Industrial Development Zone People’s Republic of China. Valid till 23-08-2023.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. HN191015-01 dated 15-10-2019 from exporter M/s Beijing Sino Hanson Import & Export Co, Ltd.No.5, Haiying road, Fengtai District, Beijing China, for import of 0.5Kg of Empagliflozin in name of M/s Neutro Pharma (Pvt) Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 08-11-2019.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>The same formulation ingredients are selected which are used by the innovator Jardiance 10mg Tablet manufactured by Boehringer Ingelheim. So Compatibility studies are not performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>EMA_t T2-21</td><td>2500 tablets</td><td>02-2021</td></tr>
<tr><td>EMA_t T3-21</td><td>2500 tablets</td><td>02-2021</td></tr>
<tr><td>EMA_t T4-21</td><td>2500 tablets</td><td>02-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Jardy tablet (10mg) of M/s CCL Pharmaceuticals</td></tr>
</table>

		Pvt. Ltd. Batch No. RJ 62 in 0.1N HCl, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Sr.#	Observations	Firm's response
1.	Provide import documents (Bills of lading; packing lists; batch certificate – Form7) of API bearing Batch number of API.	Submitted
2.	Provide reference of previous approval of applications with stability study data of the firm.	Last Product Specific Inspection of the firm was conducted for Nuvaldi 400mg Tablet, for which the inspection was conducted on 06-04-2018, the report was presented in 281st meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
3.	Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25˚C ± 2˚C / 60% ± 5%RH condition. In case where the real time stability data of drug substance is not available at 30˚C ± 2˚C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.	Firm has submitted stability study data of API as per zone IV-A conditions. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 36 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 36 & 0, 1, 2, 3 & 6 months respectively. Batches:(L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04)
4.	Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.	Submitted

Decision: Approved with Innovator's specifications.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

395.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd., 9.5 Km, Sheikhupura Road, Lahore.
	Brand Name +Dosage Form + Strength	Glifzin 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…25mg

	Diary No. Date of R& I & fee	Dy. No.41299 dated 07-12-2018; Fee Rs: 50,000/- dated 07-12-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	Packed in a unit carton in a box of 2 x 10's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	GMP certificate issued based upon inspection conducted in 14-04-2022
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxing City, Liaoning Province, China.		
API Lot No.	E-20190310-D01-E06-03		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	EMB_t T2-21	EMB_t T3-21	EMB_t T4-21
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
No. of Batches	03		
Date of Submission	26-10-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	**Not provided**
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# E-20190310-D01-E06-03) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s Neutro Pharma (Pvt) Ltd., Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone II. Stability study is conducted at Real time conditions; 25°C ± 2°C / 60% ± 5%RH for 12 months and at Accelerated conditions; 40°C ± 2°C /

		75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12 & 0, 1, 2, 3 & 6 months respectively. Batches:(20160606, 20161017,20161219)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by Liaoning Fuxin Management committee, Fluoride Industrial Development Zone People's Republic of China. Valid till 23-08-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. HN191015-01 dated 15-10-2019 from exporter M/s Beijing Sino Hanson Import & Export Co, Ltd.No.5, Haiying road, Fengtai District, Beijing China, for import of 0.5Kg of Empagliflozin in name of M/s Neutro Pharma (Pvt) Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 08-11-2019.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	The same formulation ingredients are selected which are used by the innovator Jardiance 25mg Tablet manufactured by Boehringer Ingelheim. So Compatibility studies are not performed.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** EMB_t T2-21 / 2500 tablets / 02-2021 EMB_t T3-21 / 2500 tablets / 02-2021 EMB_t T4-21 / 2500 tablets / 02-2021
11.	Record of comparative dissolution data (where applicable)	Provided Comparative dissolution was performed against Jardy tablet (25mg) of M/s CCL Pharmaceuticals Pvt. Ltd. Batch No. RK 41 in pH 1.2 HCl, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR[X]

Sr.#	Observations	Firm's response
1.	Provide import documents (Bills of lading; packing lists; batch certificate – Form7) of API bearing Batch number of API.	Submitted

	2.	Provide reference of previous approval of applications with stability study data of the firm.	Last Product Specific Inspection of the firm was conducted for Nuvaldi 400mg Tablet, for which the inspection was conducted on 06-04-2018, the report was presented in 281st meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.	
	3.	Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25°C ± 2°C / 60% ± 5%RH condition. In case where the real time stability data of drug substance is not available at 30°C ± 2°C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.	Firm has submitted stability study data of API as per zone IV-A conditions. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 36 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 36 & 0, 1, 2, 3 & 6 months respectively. Batches:(L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04)	
	4.	Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.	Submitted	

Decision: Approved with Innovator's specifications.
Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

396.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Wenopaa 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy. No.14187 dated 07-03-2019; Fee Rs: 20,000/- dated 06-03-2019
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and Technological Development zone, Huainan city, China.

API Lot No.	20190907		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 4, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-004	T-005	T-006
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	22-07-2020	22-07-2020	22-07-2020
No. of Batches	03		
Date of Submission	14-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	**Not provided**
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 20190907) of API from M/s Huainan Shunlong Pharmaceutical Co., Ltd., China and M/s Wenovo Pharmaceuticals, Taxila are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	**Not provided**
4.	Stability study data of API from API manufacturer	**Not provided**
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 29-09-2018 in the name of M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and TechnologicalDevelopment zone, Huainan city, China issued by Anhui Food and Drug Administration Anhui Pharmaceutical Profession Association China. Valid till 28-09-2023. The submitted copy of GMP certificate **could not be verified.**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not provided**
7.	Protocols followed for conduction of stability study	**Not provided**
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	The same formulation ingredients are selected which are used by the innovator Jardiance 10mg Tablet manufactured by Boehringer Ingelheim. So Compatibility studies are not performed.

10.	Complete batch manufacturing record of three stability batches.	**Not provided**
11.	Record of comparative dissolution data (where applicable)	**Not Provided**
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not provided**

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Submit stability study data of API from API manufacturer as per zone IV-A conditions.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the procurement of API with approval from DRAP.
- Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
- Dissolution test parameters are mentioned as 30 minutes sampling time whereas the acceptance limit of innovator product is testing at 15 minutes. Justify.
- Dissolution test is performed on five (5) sample units at each time point, whereas as per USP Dissolution general chapter 6 or 12 units should be tested, justify.
- Record of comparative dissolution data
- Justification for using overage in master formula.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).

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

397.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Wenopaa 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy. No.14188 dated 07-03-2019; Fee Rs: 20,000/- dated 06-03-2019
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)

	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and Technological Development zone, Huainan city, China.		
API Lot No.	20190907		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 4, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-007	T-008	T-009
Batch Size	2300 tablets	2300 tablets	2300 tablets
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	22-07-2020	22-07-2020	22-07-2020
No. of Batches	03		
Date of Submission	14-06-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	**Not provided**
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# 20190907) of API from M/s Huainan Shunlong Pharmaceutical Co., Ltd., China and M/s Wenovo Pharmaceuticals, Taxila are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	**Not provided**
4.	Stability study data of API from API manufacturer	**Not provided**
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 29-09-2018 in the name of M/s Huainan Shunlong Pharmaceutical Co., Ltd., 9th Yongxing Road, Huainan Economic and TechnologicalDevelopment zone, Huainan city, China issued by Anhui Food and Drug Administration Anhui Pharmaceutical Profession Association China. Valid till 28-09-2023. The submitted copy of GMP certificate **could not be verified.**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not provided**
7.	Protocols followed for conduction of stability study	**Not provided**

8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	The same formulation ingredients are selected which are used by the innovator Jardiance 25mg Tablet manufactured by Boehringer Ingelheim. So Compatibility studies are not performed.
10.	Complete batch manufacturing record of three stability batches.	**Not provided**
11.	Record of comparative dissolution data (where applicable)	**Not Provided**
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not provided**

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Submit stability study data of API from API manufacturer as per zone IV-A conditions.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the procurement of API with approval from DRAP.
- Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
- Dissolution test parameters are mentioned as 30 minutes sampling time whereas the acceptance limit of innovator product is testing at 15 minutes. Justify.
- Dissolution test is performed on five (5) sample units at each time point, whereas as per USP Dissolution general chapter 6 or 12 units should be tested, justify.
- Record of comparative dissolution data
- Justification for using overage in master formula.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).

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

398.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Empacor 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy. No.28171 dated 17-08-2018; Fee Rs: 20,000/- dated 17-08-2018

	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China		
API Lot No.	EPG20201001		
Description of Pack (Container closure system)	Alu-Alu blister packed in outer carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TEM-001	TEM-002	TEM-003
Batch Size	2500 tablets	2500 tablets	2300 tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	16-03-2021	16-03-2021	16-03-2021
No. of Batches	03		
Date of Submission	07-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# EPG20201001) of API from M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China and M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 06 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, & 0, 1, 2, 3 & 6 months respectively. Batches:(Z1215-170601, Z1215-170602, Z1215-170603)

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 31-03-2019 in the name of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China issued by Linhai Food and Drug Association, People's Republic of China. Valid till 30-03-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. HY201202-1 dated 21-12-2020, for import of 1.0 Kg of Empagliflozin in name of M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 18-01-2021.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** TEM-001 / 2500 tablets / 03-2021 TEM-002 / 2500 tablets / 03-2021 TEM-003 / 2500 tablets / 03-2021
11.	Record of comparative dissolution data (where applicable)	Provided Comparative dissolution was performed in acidic buffer pH 1.2, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted except summary data sheets
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

REMARKS OF EVALUATOR[X]

Initially applied with brand name "Glifloz" while submitted stability data with brand name "Empacor".

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Provide reference of previous approval of applications with stability study data of the firm.
- Specify comparator brand against which comparative dissolution has been performed.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).

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

399.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Empacor 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…25mg

	Diary No. Date of R& I & fee	Dy. No.28172 dated 17-08-2018; Fee Rs: 20,000/- dated 17-08-2018
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	2×7s; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China		
API Lot No.	EPG20201001		
Description of Pack (Container closure system)	Alu-Alu blister packed in outer carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TEG-001	TEG-002	TEG-003
Batch Size	2500 tablets	2500 tablets	2300 tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	18-03-2021	18-03-2021	18-03-2021
No. of Batches	03		
Date of Submission	07-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# EPG20201001) of API from M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China and M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 06 months and at Accelerated conditions; 40˚C ± 2˚C /

<table>
<tr><td></td><td></td><td>75% ± 5%RH for 6 months at intervals 0, 3, 6, & 0, 1, 2, 3 & 6 months respectively.
Batches:(Z1215-170601, Z1215-170602, Z1215-170603)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated 31-03-2019 in the name of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd., China issued by Linhai Food and Drug Association, People's Republic of China. Valid till 30-03-2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. HY201202-1 dated 21-12-2020, for import of 1.0 Kg of Empagliflozin in name of M/s Wimits Pharmaceuticals (Pvt.) Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 18-01-2021.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TEG-001</td><td>2500 tablets</td><td>03-2021</td></tr>
<tr><td>TEG -002</td><td>2500 tablets</td><td>03-2021</td></tr>
<tr><td>TEG -003</td><td>2500 tablets</td><td>03-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed in acidic buffer pH 1.2, Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Initially applied with brand name "Glifloz" while submitted stability data with brand name "Empacor".
<u>Shortcomings:</u>
• Latest GMP inspection report conducted within period of 3 years.
• Provide reference of previous approval of applications with stability study data of the firm.
• Specify comparator brand against which comparative dissolution has been performed.
• Record of Digital data logger for temperature and humidity monitoring of stability chambers. (accelerated and real time).</td></tr>
<tr><td colspan="3">Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.</td></tr>
<tr><td>400.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Glitz Pharma, Plot # 265, Industrial Triangle Kahuta Road Islamabad.</td></tr>
</table>

	Brand Name +Dosage Form + Strength	Lasogap-D Capsule 30mg
	Composition	Each Capsule Contains: Dexlansoprazole DDR Pellets 22.5% equivalent to Dexlansoprazole…..30mg
	Diary No. Date of R& I & fee	Dy.No 33023 dated 04-10-2018 Rs.20,000/- dated 02-10-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	30's
	Approval status of product in Reference Regulator Authorities	Dexilant 30mg capsule USFDA approved
	Me-too status	Dextop 30mg Capsule M/s Searle Pharma
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	DLP451		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 1, 3, 6 (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1260 capsules	1260 capsules	1260 capsules
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	18-12-2019	18-12-2019	18-12-2019
No. of Batches	03		
Date of Submission	16-04-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# DLP451) of API (Dexlansoprazole DD pellets 22.5%) from M/s Vision Pharma, kahuta Road, Islamabad and M/s Glitz Pharma, Islamabad are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API submitted by API manufacturer only

<table>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Submitted</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Not submitted</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. 600621 dated 03-09-2019, for import of 2.0 Kg of Dexlansoprazole DDR 22.5% pellets in name of M/s Glitz Pharma, Islamabad.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Not Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>T-001</td><td>1260 capsules</td><td>28-11-2019</td></tr>
<tr><td>T-002</td><td>1260 capsules</td><td>28-11-2019</td></tr>
<tr><td>T-003</td><td>1260 capsules</td><td>28-11-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed against Dextop capsule (30mg) of M/s The Searle Company Ltd., Karachi Batch No. 054 in 0.1N HCl, Buffer (pH 5.5) & Phosphate buffer (pH 7)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Not Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Shortcomings:
• Latest GMP inspection report conducted within period of 3 years.
• Submit reference of previous approval of applications with stability study data of the firm
• Submit method used for analysis of API from finished product manufacturer also.
• 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.
• Submit protocol followed for conduction of stability study
• Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="3">Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.</td></tr>
<tr><td>401.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Glitz Pharma, Plot # 265, Industrial Triangle Kahuta Road Islamabad.</td></tr>
</table>

	Brand Name +Dosage Form + Strength	Lasogap-D Capsule 60mg
	Composition	Each Capsule Contains: Dexlansoprazole DDR Pellets 22.5% equivalent to Dexlansoprazole…..60mg
	Diary No. Date of R& I & fee	Dy.No 33024 dated 04-10-2018 Rs.20,000/- dated 02-10-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	30's
	Approval status of product in Reference Regulator Authorities	Dexilant 60mg capsule USFDA approved
	Me-too status	Dextop 60mg Capsule M/s Searle Pharma
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	DLP451		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 1, 3, 6 (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1260 capsules	1260 capsules	1260 capsules
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	30-12-2019	30-12-2019	30-12-2019
No. of Batches	03		
Date of Submission	16-04-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# DLP451) of API (Dexlansoprazole DD pellets 22.5%) from M/s Vision Pharma, kahuta Road, Islamabad and M/s Glitz Pharma, Islamabad are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API submitted by API manufacturer only

<table>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Submitted</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Not submitted</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. 600621 dated 03-09-2019, for import of 2.0 Kg of Dexlansoprazole DDR 22.5% pellets in name of M/s Glitz Pharma, Islamabad.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Not Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
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<tr><td>T-001</td><td>1260 capsules</td><td>30-11-2019</td></tr>
<tr><td>T-002</td><td>1260 capsules</td><td>30-11-2019</td></tr>
<tr><td>T-003</td><td>1260 capsules</td><td>30-11-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed against Dextop capsule (60mg) of M/s The Searle Company Ltd., Karachi Batch No. 0034 in 0.1N HCl, Buffer (pH 5.5) & Phosphate buffer (pH 7)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Not Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not Submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Shortcomings:
• Latest GMP inspection report conducted within period of 3 years.
• Submit reference of previous approval of applications with stability study data of the firm
• Submit method used for analysis of API from finished product manufacturer also.
• 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution.
• Submit protocol followed for conduction of stability study
• Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="3">Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.</td></tr>
<tr><td>402.</td><td>Name and address of manufacturer / Applicant</td><td>M/s.AGP Limited B-23-C, S.I.T.E., Karachi.</td></tr>
</table>

	Brand Name +Dosage Form + Strength	Pixaban 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Apixaban…..... 2.5mg
	Diary No. Date of R& I & fee	Dy.No 22445 dated 29-11-2017 Rs.20,000 dated 29-11-2017, Fee Rs: 20,000/- dated 10-11-2017 vide deposit slip No.0717684.
	Pharmacological Group	Factor Xa Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10's, 20's, 60's, 168's,& 200's (4×7's); As per SRO
	Approval status of product in Reference Regulator Authorities	Eliquis 2.5mg tablet Birstol Myers Squibb Co Pharmaceutical Research institute(US FDA)
	Me-too status	Eliquis 2.5mg tablet Reg.No. 105618 Pfizer laboratories Ltd.
	GMP status	GMP certificate issued based upon inspection conducted in 12-06-2023 and valid till 11-06-2025.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	M/s. Jiangxi synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin industrial park Jiangxi Province China.		
API Lot No.	YF20190409		
Description of Pack (Container closure system)	Alu/PVC/PVDC of 1x10's and packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	TR-586	TR-587	TR588
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	18-03-2020	18-03-2020	18-03-2020
No. of Batches	03		
Date of Submission	08-07-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Glyzia-XR 50mg/500mg, 50mg/1000mg, & 100mg/1000mg tablets for which the inspection was conducted on 26-09-2018, the report was presented in 285th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# YF20190409) of API (Apixaban) from M/s. Jiangxi synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin industrial park Jiangxi Province China. and AGP Limited B-23-C, S.I.T.E., Karachi are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone II-A. Stability study is conducted at Real time conditions; 25˚C ± 2˚C / 60% ± 5%RHfor 24 months and at Accelerated conditions;40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 20-01-2022 in the name of M/s. Jiangxi synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin industrial park Jiangxi Province China issued by Jiangxi CCD Valid till 19-01-2027.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. JXSG10425 dated 23-04-2019 from M/s. Jiangxi synergy Pharmaceutical Co., Ltd. for import of 0.125kgs of Apixaban (Batch No. YF20190409) in name of M/s AGP Limited Karachi attested by AD (I&E) DRAP Karachi dated 23-04-2019.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of 03 Batches.
11.	Record of comparative dissolution data (where applicable)	Comparative dissolution was performed against Eliquis 2.5mg & Eliquis 5mg in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [X]:

Sr.#	Observations	Firm's response
1.	Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25˚C ± 2˚C / 60% ± 5%RH condition. In case where the real	Firm has submitted stability study data of API as per zone IV-B conditions. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 75% ± 5%RH for 60 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6

		time stability data of drug substance is not available at 30˚C ± 2˚C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.	months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48 & 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(20180201Y, 20180202Y, 20180203Y)	

Decision: Registration Board approved registration of Pixaban Tablet 2.5mg with Innovator's specifications by M/s AGP Limited, B-23-C, S.I.T.E., Karachi. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

403.	**Name and address of manufacturer / Applicant**	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Brand Name +Dosage Form + Strength	Pixaban Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Apixaban……..... 5mg (AGP spec's).
	Diary No. Date of R& I & fee	Dy.No 22446 dated 29-11-2017 Rs.20,000 dated 29-11-2017, Fee Rs: 20,000/- dated 10-11-2017 vide deposit slip No.0717684.
	Pharmacological Group	Factor Xa Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer Specification
	Pack size & Demanded Price	14's, 20's, 28's, 56's, 60's, 168's, 56's & 200's (4×7's); As per SRO
	Approval status of product in Reference Regulator Authorities	Eliquis 5mg tablets BRISTOL MYERS SQUIBB CO PHARMACEUTICAL RESEARCH INSTITUTE (USFDA Approved)
	Me-too status	Eliquis 5mg Tablet Pfizer Laboratories Ltd. Reg no. 105619
	GMP status	GMP certificate issued based upon inspection conducted in 12-06-2023 and valid till 11-06-2025.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	(Apixaban) M/s Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi fengxin Industrial park, Jiangxi Province, China.		
API Lot No.	(Apixaban): YF20190409		
Description of Pack (Container closure system)	Alu/PVC/PVDC of 1 x 14's blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	TR-529	TR-539	TR-540

Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	27-11-2019	27-11-2019	27-11-2019
No. of Batches	03		
Date of Submission	08-07-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Last Product Specific Inspection of the firm was conducted for Glyzia-XR 50mg/500mg, 50mg/1000mg, & 100mg/1000mg tablets for which the inspection was conducted on 26-09-2018, the report was presented in 285th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# YF20190409) of API (Apixaban) from M/s. Jiangxi synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin industrial park Jiangxi Province China. and AGP Limited B-23-C, S.I.T.E., Karachi are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone II-A. Stability study is conducted at Real time conditions; 25°C ± 2°C / 60% ± 5%RHfor 24 months and at Accelerated conditions;40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 20-01-2022 in the name of M/s. Jiangxi synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin industrial park Jiangxi Province China issued by Jiangxi CCD Valid till 19-01-2027.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. JXSG10425 dated 23-04-2019 from M/s. Jiangxi synergy Pharmaceutical Co., Ltd. for import of 0.125kgs of Apixaban (Batch No. YF20190409) in name of M/s AGP Limited Karachi attested by AD (I&E) DRAP Karachi dated 23-04-2019.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of 03 Batches.
	Record of comparative dissolution data (where applicable)	Comparative dissolution was performed against Eliquis 2.5mg & Eliquis 5mg in HCl buffer (pH

		1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
11.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
13.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [X]:

Sr.#	Observations	Firm's response
1.	Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25˚C ± 2˚C / 60% ± 5%RH condition. In case where the real time stability data of drug substance is not available at 30˚C ± 2˚C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.	Firm has submitted stability study data of API as per zone IV-B conditions. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 75% ± 5%RH for 60 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48 & 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(20180201Y, 20180202Y, 20180203Y)

Decision: Registration Board approved registration of Pixaban Tablet 5mg with Innovator's specifications by M/s AGP Limited, B-23-C, S.I.T.E., Karachi. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

b. Deferred cases

404.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy. No.40560 dated 06-12-2018;Fee Rs: 20,000/- dated 05-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK03
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)

	GMP status	-
	Remarks of the Evaluator [V]	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision of 295th meeting of RB:	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxing City, Liaoning Province, China.		
API Lot No.	E-20190920-D02-E06-01		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 1, 2, 3 (months) Real Time: 0, 3 (months)		
Batch No.	NJ-T1	NJ-T2	NJ-T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020
No. of Batches	03		
Date of Submission	30-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch# E-20190920-D02-E06-01) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s Pharmasol (Pvt) Ltd, Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished ProductManufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone II. Stability study is conducted at Real time conditions; 25°C ± 2°C / 60% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively. Batches:(20160606, 20161017,20161219)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 28-09-2018 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by

<table>
<tr><td></td><td></td><td>Fuxin Food and Drug Administration, People's Republic of China. Valid till 27-09-2020.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. 20200219-U dated 19-02-2020 from exporter M/s Beijing Sino Hanson Import & Export Co, Ltd. No.5, Haiying road, Fengtai District, Beijing China, for import of 0.5Kg of Empagliflozin (Batch No. E-20190920-D02-E06-01) in name of M/s Pharmasol (Pvt) Ltd, Lahore attested by AD (I&E) DRAP Lahore dated 05-03-2020.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not provided</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>NJ-T1</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T2</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T</td><td>2500 tablets</td><td>09-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Jardiance tablet (10mg) Batch No. C11319 in 0.1N HCl, Acetate buffer (pH 4.0) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted (only for accelerated stability)</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR[X]
Initially applied with brand name "Empazin" while submitted stability data with brand name "Empaken".
Shortcomings:
• Latest GMP inspection report conducted within period of 3 years.
• Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months.
• Provide reference of previous approval of applications with stability study data of the firm.
• Provide stability study data of API from API manufacturer as per zone IV-A conditions as the provided data is at 25°C ± 2°C / 60% ± 5%RH condition. In case where the real time stability data of drug substance is not available at 30°C ± 2°C / 65% ± 5%RH conditions, submit long term stability studies data of the drug product for 6 months along with degradation studies in the finished pharmaceutical product.
• Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
• Justify as PVP is used in formulation while in innovator product, Hydoxy Propyl Cellulose is used. Also provide Drug-excipients compatibility studies.
• Justification for using overage in master formula.</td></tr>
</table>

- Dissolution test parameters are mentioned as 20 minutes sampling time and 50rpm whereas the acceptance limit of innovator product is testing at 15 minutes and 75rpm. Justify.
- Justification for using acetate buffer (pH 4) as medium for CDP, instead of acetate buffer pH 4.5?
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time).
- Justification of performing 3rd point time test in January instead of December.

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

405.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy. No.40561 dated 06-12-2018;Fee Rs: 20,000/- dated 05-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK03
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093090)
	GMP status	-
	Remarks of the Evaluator [V]	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision of 295th meeting of RB:	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxing City, Liaoning Province, China.		
API Lot No.	E-20190920-D02-E06-01		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 1, 2, 3 (months) Real Time: 0, 3 (months)		
Batch No.	OJ-T1	OJ-T2	OJ-T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	11-09-2020	11-09-2020	11-09-2020

<table>
<tr><td colspan="2">No. of Batches</td><td>03</td></tr>
<tr><td colspan="2">Date of Submission</td><td>30-03-2021</td></tr>
<tr><td colspan="3">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>Sr. No.</td><td>Documents to Be Provided</td><td>Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Not provided</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copies of COAs (Batch# E-20190920-D02-E06-01) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s Pharmasol (Pvt) Ltd, Lahore are submitted.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of API as per zone II. Stability study is conducted at Real time conditions; 25˚C ± 2˚C / 60% ± 5%RH for 24 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively. Batches:(20160606, 20161017,20161219)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated 28-09-2018 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by Fuxin Food and Drug Administration, People’s Republic of China. Valid till 27-09-2020.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice No. 20200219-U dated 19-02-2020 from exporter M/s Beijing Sino Hanson Import & Export Co, Ltd. No.5, Haiying road, Fengtai District, Beijing China, for import of 0.5Kg of Empagliflozin (Batch No. E-20190920-D02-E06-01) in name of M/s Pharmasol (Pvt) Ltd, Lahore attested by AD (I&E) DRAP Lahore dated 05-03-2020.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not provided</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>NJ-T1</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T2</td><td>2500 tablets</td><td>09-2020</td></tr>
<tr><td>NJ-T</td><td>2500 tablets</td><td>09-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Jardiance tablet (10mg) Batch No. 906126 in 0.1N HCl, Acetate buffer (pH 4.0) & Phosphate buffer (pH 6.8)</td></tr>
</table>

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted (only for accelerated stability)

REMARKS OF EVALUATOR[X]

Initially applied with brand name "Empazin" while submitted stability data with brand name "Empaken".

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Accelerated and real time stability studies data is submitted till 3rd month time point, provide both accelerated and real time data upto 06 months.
- Provide reference of previous approval of applications with stability study data of the firm.
- Provide stability study data of API from API manufacturer as per zone IV-A conditions. In case where the real time stability data of drug substance is not available at 30°C ± 2°C / 65% ± 5%RH conditions, submit long term stability studies data of the product for 6 months along with degradation studies in the finished pharmaceutical product.
- Submit valid copy of GMP certificate of API manufacturer issued by the concerned regulatory authority of country of origin.
- Justify as PVP is used in formulation while in innovator product, Hydoxy Propyl Cellulose is used. Also provide Drug-excipients compatibility studies.
- Dissolution test parameters are mentioned as 20 minutes sampling time and 50rpm whereas the acceptance limit of innovator product is testing at 15 minutes and 75rpm. Justify.
- Justification for using acetate buffer (pH 4) as medium for CDP, instead of acetate buffer pH 4.5
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time).
- Justification of performing 3rd point time test in January instead of December.

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

406.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt. Ltd. 13-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Dexanil 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets 22.5% (Enteric Coated) eq. to Dexlansoprazole…..... 30mg
	Diary No. Date of R& I & fee	Dy.No 13050 dated 06-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulator Authorities	DEXILANT (30mg) delayed-release capsules USFDA Approved
	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976)
	GMP status	
	Remarks of the Evaluator	
	Decision of 321st meeting of RB:	Deferred for the following;

		• Specify the capsule shell material in the composition. • Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. • Latest GMP certificate/last inspection report conducted within last three years. • Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals, Kahuta Road, Islamabad		
API Lot No.	-		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	-	-	-
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	29-10-2019	29-10-2019	29-10-2019
No. of Batches	03		
Date of Submission	03-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Not Submitted**
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	**Not Submitted**
4.	Stability study data of API from API manufacturer	**Not Submitted**
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not Submitted**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A, **purchase documents not submitted**
7.	Protocols followed for conduction of stability study	**Not Submitted**
8.	Method used for analysis of FPP	**Not Submitted**
9.	Drug-excipients compatibility studies (where applicable)	N/A

10.	Complete batch manufacturing record of three stability batches.	**Not Submitted**
11.	Record of comparative dissolution data (where applicable)	**Not Submitted**
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted **except chromatograms and COAs** etc.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	**Not Submitted**
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Submitted**

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.
- Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Stability study data of API from API manufacturer
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the purchase of API
- Protocols followed for conduction of stability study
- Method used for analysis of FPP
- Complete batch manufacturing record of three stability batches.
- Record of comparative dissolution data (where applicable)
- Data of 03 batches will be supported by attested respective documents like chromatograms, COA, etc.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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

407.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt. Ltd. 13-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Dexanil 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets 22.5% (Enteric Coated) eq. to Dexlansoprazole…..... 60mg
	Diary No. Date of R& I & fee	Dy.No 11483 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulator Authorities	DEXILANT (60mg) delayed-release capsules USFDA Approved

	Me-too status	Razodex 60mg capsule by M/s Getz Pharma (Reg#086975)
	GMP status	
	Remarks of the Evaluator [XI]	• The firm submitted source of pellets, along with stability studies data of three batches as per zone IV-A, COA, GMP certificate from vision pharma. • The firm did not submit stability study data of three batches as per guidelines approved in 293rd meeting of Registration Board.
	Decision of 312th meeting of RB:	Deferred for submission of stability study data of three batches as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals, Kahuta Road, Islamabad		
API Lot No.	-		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	-	-	-
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	29-10-2019	29-10-2019	29-10-2019
No. of Batches	03		
Date of Submission	03-03-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Not Submitted**
3.	Method used for analysis of API from both API Manufacturer and Finished ProductManufacturer	**Not Submitted**
4.	Stability study data of API from API manufacturer	**Not Submitted**
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not Submitted**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A, purchase documents not submitted

7.	Protocols followed for conduction of stability study	Not Submitted
8.	Method used for analysis of FPP	Not Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	**Not Submitted**
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted except chromatograms and COAs etc.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

REMARKS OF EVALUATOR[X]

Shortcomings:

- Latest GMP inspection report conducted within period of 3 years.
- Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.
- Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Stability study data of API from API manufacturer
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the purchase of API
- Protocols followed for conduction of stability study
- Method used for analysis of FPP
- Complete batch manufacturing record of three stability batches.
- Record of comparative dissolution data (where applicable)
- Data of 03 batches will be supported by attested respective documents like chromatograms, COA, etc.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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

Agenda of Evaluator PEC-XI

Case No. 01; Deferred routine registration applications of Human Drugs on Form 5F

408.	Name, address of Applicant / Marketing Authorization Holder	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 8300 dated 30-03-2022
	Details of fee submitted	Rs.50,000/- dated 25-02-2021
	The proposed proprietary name / brand name	**Mek-Min 1ml Ampoule Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Mecobalamin…..... 500mcg
	Pharmaceutical form of applied drug	IV/IM
	Pharmacotherapeutic Group of (API)	Vitamins
	Reference to Finished product specifications	Neutro's specifications
	Proposed Pack size	1mlx10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methycobal injection 500µg PMDA Japan Approved
	For generic drugs (me-too status)	Mecovex 500mcg injection by M/s Novex Pharmaceuticals (Reg# 99639)
	Name and address of API manufacturer.	M/s Mahima Life Sciences Pvt. Ltd., BT Road, Ganaur-131101 Sonepat, Haryana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturingprocess and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. (Batches; MLMCB-361113, MLMCB-381113, MLMCB-391213)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Methycobal Injection 1ml by M/s Hilton Pharma by performing quality tests (Description, identification, pH, sterility, BET and assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including precision (repeatability, intermediate), linearity, ruggedness, LOD, LOQ, robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Mahima Life Sciences Pvt. Ltd., BT Road, Ganaur-131101 Sonepat, Haryana India		
API Lot No.	MLMCB-050318		
Description of Pack (Container closure system)	A red to dark red color solution, filled in amber glass printed ampoule of USP type I/II, thermally sealed, placed in a honey comb tray as 1x10 ampoules and packed in a unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	5000 ampoules	5000 ampoules	5000 ampoules
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	02-03-2020	02-03-2020	02-03-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP M/s Mahima Life Sciences Pvt. Ltd., BT Road, Ganaur-131101 Sonepat, Haryana India issued by Food & Drugs Administration Haryana India valid upto two years from date of issue. (Date of issue;13-09-2019-8)

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 163/MAH/19-20 dated 19-01-2020 for import of 01kg of Mecobalamin JP (Batch# MLMCB-030120) in name of M/s Neutro Pharma. *However the invoice is not attested by AD (I&E) field office. (mfg date of API; 01/2020)*
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 10th March 2022. (almost 1 year before R&I date) • Fee of only Rs. 50000/- is submitted for contract manufacturing
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product (**reference product**; Mecobalamin, D-mannitol….. **Applied product;** Mecobalamin, Disodium Edetate, D-Mannitol, Phenyl Mercuric Nitrate, WFI**)**
3.2.P.3	• Calculation for dispensed quantity of API in master formulation shall be submitted
3.2.P.5	• Justification shall be submitted for selecting different limit of pH test (4.5-7.0) in finished product specifications than that recommended by innovator product review document (5.3-7.3). • Results of analytical method validation studies including accuracy and specificity shall be submitted

3.2.P.8	• Submit documents for procurement of API with approval from DRAP • The batch No. of API in batch analysis of drug substance (MLMCB-050318, mfg date 03-2018) is different from that submitted in commercial invoice (Batch# MLMCB-030120), clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferrement Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 25-02-2021 while R&I date of submitted application is 10th March 2022. (almost 1 year before R&I date) • Fee of only Rs. 50000/- is submitted for contract manufacturing	• The firm submitted that fee is submitted on 25-12-2021 and R&I date of submitted application is 30-03-2022. There is only 3 months difference between fee submission date and R&I date, not 1 year. • The statement of firm is not according to submitted documents as fee submitted date is 25-02-2021. Furthermore firm has submitted only Rs. 50000/- fee for contract manufacturing.
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. Applicant details: M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore Manufacturer details: M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F we have mistakenly submitted that applicant is manufacturer, actually applicant is contract giver. It might be a typographical error.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority(Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Liquid Injection Ampoule / Vial (General Section

1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP M/s Mahima Life Sciences Pvt. Ltd., BT Road, Ganaur, Distt. Sonepat, (Haryana) India issued by Food & Drugs Administration Haryana India valid upto 12-09-2024
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performedby the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product (**reference product**; Mecobalamin, D-mannitol…... **Applied product;** Mecobalamin, Disodium Edetate, D-Mannitol, Phenyl Mercuric Nitrate, WFI**)**	• Drug-Excipient compatibility study is submitted
3.2.P.3	• Calculation for dispensed quantity of API in master formulation shall be submitted	• Calculation for dispensed quantity of API in master formulation is submitted
3.2.P.5	• Justification shall be submitted for selecting different limit of pH test (4.5-7.0) in finished product specifications than that recommended by innovator product review document (5.3-7.3). • Results of analytical method validation studies including accuracy and specificity shall be submitted	• No justification is submitted, instead finished product specifications is submitted again in which limits of pH test has been revised as per innovator product review document (5.3-7.3). • Firm has submitted results of analytical method validation studies including specificity, accuracy, linearity and range, precision, robustness, LOD and LOQ.
3.2.P.8	• Submit documents for procurement of API with approval from DRAP • The batch No. of API in batch analysis of drug substance (MLMCB-050318, mfg date 03-2018) is different from that submitted in commercial invoice (Batch# MLMCB-030120), clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of invoice No. 163/MAH/19-20 dated 19-01-2020 for import of 01kg of Mecobalamin JP (Batch# MLMCB-030120) in name of M/s Neutro Pharma. *However the invoice is not attested by AD (I&E) field office.* • No clarification is submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Differential fee of Rs. 25,000/- for contract manufacturer, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**

• **Documents for procurement of API with approval from DRAP** • **Clarification since the batch No. of API in batch analysis of drug substance (MLMCB-050318, mfg date 03-2018) is different from that submitted in commercial invoice (Batch# MLMCB-030120)**		
409.	Name, address of Applicant / Marketing Authorization Holder	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6376 dated 08-03-2022
	Details of fee submitted	Rs.50,000/- dated 12-05-2020
	The proposed proprietary name / brand name	**Apozole 600mg Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 300ml Contains: Linezolid… 600mg
	Pharmaceutical form of applied drug	IV infusion
	Pharmacotherapeutic Group of (API)	Synthetic Antibiotic
	Reference to Finished product specifications	Neutro's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZYVOX (600mg/300mL) I.V injection, USFDA Approved
	For generic drugs (me-too status)	Ecasil 600mg/300ml Infusion by M/s SAMI Pharmaceuticals (Reg# 67518)
	Name and address of API manufacturer.	M/s Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturingprocess and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. (Batches; OT-LID-S2-002/16, OT-LID-S2-003/16, OT-LID-S2-004/16) The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 9 months. (Batches; OP-LNZ-A1-001/20, OP-LNZ-A1-002/20, OP-LNZ-A1-003/20)
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Ecosil Infusion 300ml by M/s Sami Pharmaceutical by performing quality tests (Description, identification, pH, sterility, BET and assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including precision (repeatability, intermediate), linearity, and accuracy.

STABILITY STUDY DATA

Manufacturer of API	M/s Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.		
API Lot No.	OT-LID/01/20/011		
Description of Pack (Container closure system)	A clear, an almost colorless to pale yellow color solution, filled in a clear glass/LDPE 100ml sterile bottle neatly labelled and packed in a unit carton with plastic hanger and a leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	500 packs	500 packs	500 packs

Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	17-03-2020	17-03-2020	17-03-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP M/s Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India, issued by Drugs Control Administration Telangana India valid upto 14-09-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 1920OT135/EXP dated 20-01-2020 for import of 02kg of Linezolid (Batch# OT-LID/01/20/011) in name of M/s Neutro Pharma attested by AD (I&E) DRAP Lahore dated 27-01-2020. *(mfg date of API; Oct 2019)*
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 12-05-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year & 09 months before R&I date)
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.5.5	• Indicate Pharmacological class of the API (drug substance) with proper reference
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.

3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product (**reference product**; dextrose monohydrate, sodium citrate dihydrate, citric acid anhydrous. Sodium hydroxide NF and/or hydrochloric acid NF **Applied product;** dextrose anhydrous, sodium citrate dihydrate, citric acid anhydrous, Sodium hydroxide, Sodium chloride, WFI**)**
3.2.P.3	• Clarification is required as you have mentioned the use of 1.1% overage in master formulation • Innovator drug product is using sodium hydroxide and/or hydrochloric acid for attaining the pH within a narrow range of 4.4-5.2 while your master formulation does not specify the use of hydrochloric acid. Justification is required in this regard.
3.2.P.5	• Justification shall be submitted as analytical procedure for assay test is submitted as per UV method while method validation studies is submitted as per HPLC method • Results of analytical method validation studies including Specificity, Limit of Detection, Limit of Quantitation, Range and robustness shall be submitted • Justification shall be submitted for not performing the test for filled volume and particulate matter in batch analysis of the finished product as per submitted specifications.
3.2.P.7	• The applied label claim is for 300ml while applied pack size is 100ml, clarify?
3.2.P.8	• The mobile phase ratio mentioned in raw data sheet is water;ACN (30;70) while water;ACN (50;50) in analytical method validation, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	Deferrement Reason	Firm's Response
1.1	• Clarification is required as the fee is submitted on 12-05-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year & 09 months before R&I date)	• The firm submitted that fee is submitted on 12-05-2020 and R&I date of submitted application is 08-03-2022, because initially our file was R&I on 05-11-2020, but our file was deferred in pre submission screening of CTD. We again submitted our application on 08-03-2022 along with deficient documents and deficient fee Rs. 25000/- on deposit slip#421746134 date 04-02-2022.
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. Applicant details: M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore Manufacturer details: M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore

	1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F we have mistakenly submitted that applicant is manufacturer, actually applicant is contract giver. It might be a typographical error.	
	1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Liquid Injection Ampoule / Vial (General Section and LVP section	
	1.5.5	• Indicate Pharmacological class of the API (drug substance) with proper reference	• Monoamine Oxidase Inhibitors (MAO Inhibitor). However, it belong to Other antibacterials group ATC Code; J01XX08	
	1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has not submitted valid copy of cGMP/DML of Drug substance manufacturer. • However the firm has submitted copy of letter for change of company name from M/s Optrix Laboratories Pvt Ltd. To M/s Optimus drugs Private Limited., Unit III, Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India, issued by Drugs Control Administration Telangana India in which it is stated that license is valid upto 02-06-2025	
	2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 is submitted	

	3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.	
	3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted	• Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.	
	3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product (**reference product**; dextrose monohydrate, sodium citrate dihydrate, citric acid anhydrous. Sodium hydroxide NF and/or hydrochloric acid NF .....**Applied product;** dextrose anhydrous, sodium citrate dihydrate, citric acid anhydrous, Sodium hydroxide, Sodium chloride, WFI**)**	• Drug-Excipient compatibility study is submitted	
	3.2.P.3	• Clarification is required as you have mentioned the use of 1.1% overage in master formulation • Innovator drug product is using sodium hydroxide and/or hydrochloric acid for attaining the pH within a narrow range of 4.4-5.2 while your master formulation does not specify the use of hydrochloric acid. Justification is required in this regard.	• No clarification is submitted	
	3.2.P.5	• Justification shall be submitted as analytical procedure for assay test is submitted as per UV method while method validation studies is submitted as per HPLC method • Results of analytical method validation studies including Specificity, Limit of Detection, Limit of Quantitation, Range and robustness shall be submitted • Justification shall be submitted for not performing the test for filled volume and particulate matter in batch analysis of the finished product as per submitted specifications.	• Firm has submitted revised analytical method in which procedure of assay test is submitted as per HPLC method. • Results of analytical method validation studies including Specificity, linearity and range, robustness, Limit of Detection, Limit of and system suitability is submitted • Firm has submitted revised batch analysis report in which test for filled volume and particulate matter is performed	
	3.2.P.7	• The applied label claim is for 300ml while applied pack size is 100ml, clarify?	• The firm submitted that the applied pack size is 300ml	

	3.2.P.8	• The mobile phase ratio mentioned in raw data sheet is water;ACN (30;70) while water;ACN (50;50) in analytical method validation, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• No justification is submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted	

Decision: Deferred for submission of following:

- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Clarification as you have mentioned the use of 1.1% overage in master formulation**
- **Justification as innovator drug product is using sodium hydroxide and/or hydrochloric acid for attaining the pH within a narrow range of 4.4-5.2 while your master formulation does not specify the use of hydrochloric acid.**
- **Clarification as the mobile phase ratio mentioned in raw data sheet is water;ACN (30;70) while water;ACN (50;50) in analytical method validation**

410.	Name, address of Applicant / Marketing Authorization Holder	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd., 9.5km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	M/s Neutro Pharma: Firm has submitted copy of cGMP certificate dated 11-07-2019 based on inspection conducted on 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of cGMP certificate dated 11-07-2019 specifying Injectable section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 6130 dated 07-03-2022
	Details of fee submitted	Rs.50,000/- dated 27-11-2020
	The proposed proprietary name / brand name	**Klazol 500mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Metronidazole 500mg
	Pharmaceutical form of applied drug	IV Infusion
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1x100ml
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	METRONIDAZOLE NORIDEM, metronidazole 500mg/100mL solution for injection bottle TGA Approved
	For generic drugs (me-too status)	Macneda 500mg/100ml Infusion by M/s Searle IV Solutions (Reg# 105957)
	Name and address of API manufacturer.	M/s Hubei Hongyuan Pharmaceuticals Co., Ltd., No. 8 Fengshan Road, Industrial and Economic Development Zone Luotian County, Huanggang City, Hubei Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturingprocess and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. (Batches; 031201, 031202, 031203) The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. (Batches: 070101, 070102, 070103) *However the test sample is manufactured by Luotian Hongyuan Biochemical Co., Ltd*
	Module-III (Drug Product):	Firm has submitted data of drug product including description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Flagyl infusion 100ml by M/s Sanofi Aventis Pakistan by performing quality tests (Description, identification, pH, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability,

		intermediate), linearity, ruggedness.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Hubei Hongyuan Pharmaceuticals Co., Ltd., No. 8 Fengshan Road, Industrial and Economic Development Zone Luotian County, Huanggang City, Hubei Province, China		
API Lot No.		20140149		
Description of Pack (Container closure system)		A clear, an almost colorless to pale yellow color, sterile solution filled in a clear glass vial of USP type I/II, sealed with rubber closure, neatly labelled		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		MET-INF-100-001-19	MET-INF-100-002-19	MET-INF-100-003-19
Batch Size		500 vials	500 vials	500 vials
Manufacturing Date		09-2019	09-2019	09-2019
Date of Initiation		01-10-2019	03-10-2019	07-10-2019
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Hubei Hongyuan Pharmaceuticals Co., Ltd.,(**1.** No.126 Dabiseshan Road, Industrial and Economic Development Zone, Luotian County, Huanggang City, Hubei Province, China; **2**. No. 3 Hongyuan Road, Fengshan Town, Luotian County,Huanggang City, Hubei Province, China issued by Hubei Provincial Food and Drug Administration China valid upto 30-07-2023		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No#20LHY293 dated 13-05-2020 for import of 500kg of Metronidazole (Batch No#0182005170) in name of M/s Neutro Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 28-05-2020.		
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, UV spectra and summary data sheets etc.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted		

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Clarification is required as the fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year & 11month before R&I date)

	• Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority (Section ampoule or vial).
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.S.7	• Submit Stability study data of drug substance from drug substance manufacture till claimed shelf life
3.2.P.1	• In description and composition of drug product *each capsule contains; cefalexin as monohydrate…..500mg* while applied product is metronidazole infusion, clarify?
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation
3.2.P.5	• The concentration of sample solution (0.05 instead of 0.02mg/ml) and solvent used for dilution (water instead of 0.1M HCl) in assay test of finished product are different than that recommended by BP monograph. • Submit results for specificity test in method validation studies • Justification shall be submitted for selecting different limits of pH test 4.5-7.0 in batch analysis of finished product than that submitted in finished product specifications (4.5-6.0) as per BP monograph and results of batch No# MET-INF-100-003-19 is 6.86 which is out specifications • Justification shall be submitted for selecting different limits of endotoxin test NMT 0.7 IU/ml in batch analysis of finished product than that submitted in finished product specifications (NMT 3.5IU/ml) as per BP monograph
3.2.P.8	• *Clarification is required as the expiry date of drug substance as per submitted COA by drug substance manufacturer and drug product manufacturer is 01-2018 which is prior to the manufacturing date (10-2019) of trial batches (as per submitted stability summary sheets)* • The batch No. of API in batch analysis is different from that submitted in commercial invoice, clarify • Batch No. of drug product mentioned on stability summary sheet is 001, 002, 003 instead of MET-INF-100-001-19, MET-INF-100-002-19 and MET-INF-100-003-19 as mentioned in batch analysis, clarify • Batch size of drug product mentioned in stability summary sheet is 4500 and 5000 vials instead of 500vials as mentioned in batch analysis, clarify • Manufacturing date of drug product mentioned in stability summary sheet is 10-2019 in all batches instead of 09-2019 as mentioned in batch analysis, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required
Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings	

Response of the firm:		
Section	**Deferment Reason**	**Firm's Response**
1.1	• Clarification is required as the fee is submitted on 30-04-2020 while R&I date of submitted application is 08th March 2022. (almost 1 year & 11month before R&I date) • Submit differential fee for contract manufacturing of applied product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	• The firm submitted that fee is submitted on 27-11-2020 and R&I date of submitted application is 08-03-2022. • We initially submitted our application on 29-12-2020, but some deficiencies were found in pre submission screening of CTD. We re-submitted our application on 07-03-2022 along with deficient documents. That's why there is difference between fee submission date and R&I sate of document. • Firm has submitted fee Rs. 25000/- on deposit slip#1890069346 date 30-10-2023.
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s Radiant Pharma Pvt Ltd	• The firm has submitted details of applicant and manufacturer in module 1 of form 5F. Applicant details: M/s Radiant Pharma (Pvt) Ltd., 43-E, Sundar Industrial Estate, Raiwand Road, Lahore Manufacturer details: • M/s Neutro Pharma (Pvt) Ltd., 9.5-km Sheikhupura Road, Lahore
1.3.3	You have submitted that applicant is Manufacturer and Is involved in none of the above (contract giver) in form 5F clarify	The firm submitted that in form 5F it is mistakenly written while applicant is contract giver. It might be a typographical error.
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years • Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority(Section ampoule or vial).	• **M/s Radiant Pharma (Pvt) Ltd** The firm has not submitted copy of cGMP certificate or GMP inspection report. However the firm has submitted a copy of letter addressed to Additional Director DRAP Lahore dated 21-08-2023 for issuance of cGMP certificate and inspection of M/s Radiant Pharma • **M/s Neutro Pharma (Pvt):** Firm has submitted copy of cGMP certificate dated 30-06-2022 based on inspection conducted on 14-04-2022. • Firm has submitted copy of letter of M/s Neutro Pharma dated 04-07-2022 specifying Liquid Injection Ampoule / Vial (General Section) and LVP section (Blow, Fill, Seal)
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin is required	• The firm has submitted copy of cGMP certificate of M/s Hubei Hongyuan Pharmaceutical Technology Co., Ltd., No. 8 Hongyuan Road, Fengshan town Industrial and Economic Development Zone Luotian County, Huanggang City, Hubei Province, China issued by State Food & Drugs Administration China valid upto 01-01-2024

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performedby the Drug Product manufacturer for drug substance is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.S.7	• Submit Stability study data of drug substance from drug substance manufacture till claimed shelf life	• Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 60 months. The stability study data is not as per zone VI-A conditions • Furthermore firm has submitted that manufacturer of test sample is manufactured by M/s Luotian Hongyuan Biochemical Co., Ltd.
3.2.P.1	• In description and composition of drug product *each capsule contains; cefalexin as monohydrate…..500mg* while applied product is metronidazole infusion, clarify?	• Firm has submitted details of applied product metronidazole infusion in description and composition of drug product
3.2.P.3	• Clarification is required as you have mentioned the use of 1% overage in master formulation	• The firm has not submitted any clarification
3.2.P.5	• The concentration of sample solution (0.05 instead of 0.02mg/ml) and solvent used for dilution (water instead of 0.1M HCl) in assay test of finished product are different than that recommended by BP monograph. • Submit results for specificity test in method validation studies • Justification shall be submitted for selecting different limits of pH test 4.5-7.0 in batch analysis of finished product than that submitted in finished product specifications (4.5-6.0) as per BP monograph and results of batch No# MET-INF-100-003-19 is 6.86 which isout specifications • Justification shall be submitted for selecting different limits of endotoxin test NMT 0.7 IU/ml in batch analysis of finished product than that submitted in	• Firm has submitted revised analytical method in which the concentration of solution and solvent used for dilution in assay test of finished product is as per BP monograph • Firm has submitted results of specificity, accuracy and repeatability test in method verification studies • The firm has not submitted any justification. However, the firm has submitted revised batch analysis report of three batches of finished product in which the limits of pH test is as per BP monograph (4.5-6.0) and results of pH in all three batches are within limits. • The firm has not submitted any justification. However, the firm has submitted revised batch analysis report of three batches of finished product in which limits of endotoxin test of finished product is as per BP monograph (NMT 3.5IU/ml)

	finished product specifications (NMT 3.5IU/ml) as per BP monograph	
3.2.P.8	• *Clarification is required as the expiry date of drug substance as per submitted COA by drug substance manufacturer and drug product manufacturer is 01-2018 which is prior to the manufacturing date (10-2019) of trial batches (as per submitted stability summary sheets)* • The batch No. of API in batch analysis is different from that submitted in commercial invoice, clarify • Batch No. of drug product mentioned on stability summary sheet is 001, 002, 003 instead of MET-INF-100-001-19, MET-INF-100-002-19 and MET-INF-100-003-19 as mentioned in batch analysis, clarify • Batch size of drug product mentioned in stability summary sheet is 4500 and 5000 vials instead of 500vials as mentioned in batch analysis, clarify • Manufacturing date of drug product mentioned in stability summary sheet is 10-2019 in all batches instead of 09-2019 as mentioned in batch analysis, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• *No justification is submitted.* However the firm has submitted another COA from drug substance manufacturer (Batch#0182005170) in which the expiry date of drug substance is after manufacturing of trial batches and batch No. of API is different from that already submitted in dossier. • *No clarification is submitted.* However, Firm has again submitted copy of commercial invoice No#20LHY293 dated 13-05-2018 for import of 500kg of Metronidazole (Batch No#0182005170) in name of M/s Neutro Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 28-05-2018. The dates on the submitted invoice have been overwritten hence the actual date ofattestation could not be established. The manufacturing date of API mentioned in invoice in 14/May/2018 while date of invoice is 13/May/2018. • The firm has submitted revised batch analysis report in which Batch No. of drug product is mentioned as 001, 002, 003 as per stability summary sheet. • The firm has submitted revised batch analysis report in batch size of batch No#001 and 003 is 4500 vials while batch size of batch No#002 is 5000 vials • The firm has submitted revised batch analysis report in which manufacturing date of all batches is 10-2019 as per stability summary sheets • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s Radiant Pharma (Pvt) Ltd conducted with in last three years**
- **Stability study data of drug substance from drug substance manufacture till claimed shelf life**
- **Clarification as you have mentioned the use of 1% overage in master formulation**
- **Clarification is required as the expiry date of drug substance as per submitted COA by drug substance manufacturer and drug product manufacturer is 01-2018 which is prior to the manufacturing date (10-2019) of trial batches (as per submitted stability summary sheets)**
- **Clarification for submitting another COA from drug substance manufacturer (Batch#0182005170) in which the expiry date of drug substance is after manufacturing of trial batches and batch No. of API is different from that already submitted in dossier.**
- **Verification of commercial invoice No#20LHY293 dated 13-05-2018 for import of 500kg of Metronidazole (Batch No#0182005170) in name of M/s Neutro Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 28-05-2018. The dates on the submitted invoice have been overwritten hence the actual date of attestation could not be established.**

411.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals (Pvt.) Ltd., 65 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-km, Ferozepur Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	**M/s CCL Pharmaceuticals:** Firm has submitted copy of cGMP certificate dated 13-05-2019 based on inspection conducted on 30-04-2019. **M/s Dyson Research Laboratories:** Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML (section approval) dated 08-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8631 dated 04-04-2022
	Details of fee submitted	PKR 75,000/- Dated 07-02-2022 (Deposit slip#98970448185)
	The proposed proprietary name / brand name	**Obeticholic 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid..... 5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OCALIVA (5mg, 10mg) film coated tablets USFDA
	For generic drugs (me-too status)	Abeticholic 5mg Tablet of M/s Dyson Research laboratories (Reg. No. 109521)
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months. (Batches: 201612001, 201612002, 201612003)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Ocaliva 5mg Tablet manufactured by M/s Intercept Pharma UK & Ireland by performing quality tests (Description, identification, dissolution, assay). Firm has submitted CDP results of their product against the innovator's product Ocaliva 5mg Tablet by M/s Intercept Pharma UK & Ireland in 0.1N HCl (pH 1.2) Acetate buffer (pH 4.5), & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Linearity, Accuracy, Precision, Specificity, Repeatability, Robustness,

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road,Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China		
API Lot No.	RD-OLAB-202104251		
Description of Pack (Container closure system)	Alu-alu Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	T01	T02	T03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet

Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	22-10-2021	22-10-2021	22-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China issued by Nantong Chemical & Medical Industry Association valid upto 05-05-2022. Firm has also submitted copy of DML (License#Su20160512) of M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, China issued by Jiangsu Drug Administration valid upto 02-12-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) for 3 months is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years	•
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Justification shall be submitted for not including the test for sulphated ash, palladium content, particle size distribution, and solid state form in drug substance specifications by drug product manufacturer	•
3.2.S.7	• Submit stability study data of drug substance at real time conditions till claimed shelf life • Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance	•
3.2.P.1	• Details of composition for 10mg strength is submitted	•
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document (uniformity of dosage units and water content) • Details of innovator product i.e. manufacturer, batch number, manufacturing date and expiry date shall be submitted	•

	• Submitted CDP results in three dissolution media shall be justified against the solubility profile of drug substance with reference to innovator drug product literature	
3.2.P.5	• Justification shall be submitted for not including the test for water content in finished product specification as per innovator product review document • Justification shall be submitted for selecting the sampling time of 45min while dissolution specifications of NLT Q after 15min • Clarification is required as you have mentioned dissolution test (UV) in analytical method while provided chromatographic conditions for the same test	•
3.2.P.8	• Submit 6th month time point stability study data for the applied drug product • Submit documents for procurement of API with approval from DRAP • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	•

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of firm:

Section	Deferment Reason	Firm's Response
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years	• **M/s CCL Pharmaceuticals:** cGMP certificate of M/s CCL Pharmaceuticals is not submitted. • **M/s Dyson Research Laboratories:** Firm has submitted copy of cGMP certificate dated 16-01-2023 based on inspection conducted on 03-11-2022.
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML (License#Su20160512) of M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, China issued by Jiangsu Drug Administration valid upto 02-12-2025
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Justification shall be submitted for not including the test for sulphated ash, palladium content, particle size distribution, and solid state form in drug substance specifications by drug product manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted. • Drug substance manufacturer has not mentioned these tests in specifications and analytical method of drug substance. That is why test for sulphated ash, palladium content, particle size distribution, and solid state form are not included in drug substance specifications.
3.2.S.7	• Submit stability study data of drug substance at real time conditions till claimed shelf life • Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance	• Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. • Drug substance manufacturer has conducted stability study as per zone IV-A for drug substance and the stability data shows that product is stable. Drug substance manufacturer has not recommended 5°C storage conditions.

3.2.P.1	• Details of composition for 10mg strength is submitted	• Revised details of composition for 5mg strength is submitted.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document (uniformity of dosage units and water content) • Details of innovator product i.e. manufacturer, batch number, manufacturing date and expiry date shall be submitted • Submitted CDP results in three dissolution media shall be justified against the solubility profile of drug substance with reference to innovator drug product literature	• Revised pharmaceutical equivalence after adding uniformity of dosage form and water content is submitted. • The firm submitted that we have performed studies against Dyson's own (as competitor) registered product Abeticholic Acid 5mg Tablet, registration no. 109521, Batch No. DY001, Mfg. Oct 2021, Expiry Oct 2023. • The firm submitted that we have performed studies against Dyson's own (as competitor) registered product Abeticholic Acid 5mg tablet, and as per that product complies with specifications.
3.2.P.5	• Justification shall be submitted for not including the test for water content in finished product specification as per innovator product review document • Justification shall be submitted for selecting the sampling time of 45min while dissolution specifications of NLT Q after 15min • Clarification is required as you have mentioned dissolution test (UV) in analytical method while provided chromatographic conditions for the same test	• Revised specifications after including test for water content in FP specifications is submitted. • The firm submitted that it was a typographic error as our specifications are as per innovator's product specifications. • The firm submitted that it was a typographic error.
3.2.P.8	• Submit 6th month time point stability study data for the applied drug product • Submit documents for procurement of API with approval from DRAP • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• 6th month time point stability data for drug product is submitted. • Firm has submitted copy of commercial invoice for import of Obeticholic acid quantity 3kg by M/s Dyson Research Laboratories Lahore attested by AD (I&E) DRAP Lahore dated 24-09-2021. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Decision: Deferred for submission of following:

- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **GMP certificate / GMP inspection report of applicant i.e. M/s CCL Pharmaceuticals conducted with in last three years**
- **Pharmaceutical equivalence and CDP studies against the innovator/reference/comparator product**

412.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals (Pvt.) Ltd., 65 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-km, Ferozepur Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the Finished product manufacturer	**M/s CCL Pharmaceuticals:** Firm has submitted copy of cGMP certificate dated 13-05-2019 based on inspection conducted on 30-04-2019. **M/s Dyson Research Laboratories:** Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML (section approval) dated 08-06-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8632 dated 04-04-2022
	Details of fee submitted	PKR 75,000/- Dated 07-02-2022 (Deposit slip#59446592504)
	The proposed proprietary name / brand name	**Obeticholic 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid..... 10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OCALIVA (5mg, 10mg) film coated tablets USFDA
	For generic drugs (me-too status)	Abeticholic 10mg Tablet of M/s Dyson Research laboratories (Reg. No. 109522)
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months. (Batches: 201612001, 201612002, 201612003)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Ocaliva 10mg Tablet manufactured by M/s Intercept Pharma UK & Ireland by performing quality tests (Description, identification, dissolution, assay). Firm has submitted CDP results of their product against the innovator's product Ocaliva 10mg Tablet by M/s Intercept Pharma UK & Ireland in 0.1N HCl (pH 1.2) Acetate buffer (pH 4.5), & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Linearity, Accuracy, Precision, Specificity, Repeatability, Robustness,

STABILITY STUDY DATA			
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China		
API Lot No.	RD-OLAB-202104251		
Description of Pack (Container closure system)	Alu-alu Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	T01	T02	T03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	22-10-2021	22-10-2021	22-10-2021
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China issued by Nantong Chemical & Medical Industry Association valid upto 05-05-2022. Firm has also submitted copy of DML (License#Su20160512) of M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, China issued by Jiangsu Drug Administration valid upto 02-12-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) for 3 months is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years	•
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Justification shall be submitted for not including the test for sulphated ash, palladium content, particle size distribution, and solid state form in drug substance specifications by drug product manufacturer	•
3.2.S.7	• Submit stability study data of drug substance at real time conditions till claimed shelf life • Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance	•
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document (uniformity of dosage units and water content) • Details of innovator product i.e. manufacturer, batch number, manufacturing date and expiry date shall be submitted • Submitted CDP results in three dissolution media shall be justified against the solubility profile of drug substance with reference to innovator drug product literature	•
3.2.P.5	• Justification shall be submitted for not including the test for water content in finished product specification as per innovator product review document	•

		• Justification shall be submitted for selecting the sampling time of 45min while dissolution specifications of NLT Q after 15min	
	3.2.P.8	• Submit 6th month time point stability study data for the applied drug product • Submit documents for procurement of API with approval from DRAP • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	•

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of firm:

Section	Observations	Response
1.3.5	• Submit GMP certificate / GMP inspection report of both applicant & manufacturing unit conducted with in last three years	• **M/s CCL Pharmaceuticals:** cGMP certificate of M/s CCL Pharmaceuticals is not submitted. • **M/s Dyson Research Laboratories:** Firm has submitted copy of cGMP certificate dated 16-01-2023 based on inspection conducted on 03-11-2022.
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML (License#Su20160512) of M/s Nantong Chanyoo Pharmatech Co., Ltd, No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, China issued by Jiangsu Drug Administration valid upto 02-12-2025
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Justification shall be submitted for not including the test for sulphated ash,palladium content, particle size distribution, and solid state form in drug substance specifications by drug product manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufactureris submitted. • Drug substance manufacturer has not mentioned these tests in specifications and analytical method of drug substance. That is why test for sulphated ash, palladium content, particle size distribution, and solid state form are not included in drug substance specifications.
3.2.S.7	• Submit stability study data of drug substance at real time conditions till claimed shelf life • Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance	• Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. • Drug substance manufacturer hasconducted stability study as per zone IV-A for drug substance and the stability data shows that product is stable. Drug substance manufacturer has not recommended 5°C storage conditions.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document (uniformity of dosage units and water content)	• Revised pharmaceutical equivalence after adding uniformity of dosage form and water content is submitted. • The firm submitted that we have performed studies against Dyson's own (as competitor) registered product Abeticholic Acid 10mg Tablet, registration no. 109522,

	• Details of innovator product i.e. manufacturer, batch number, manufacturing date and expiry date shall be submitted • Submitted CDP results in three dissolution media shall be justified against the solubility profile of drug substance with reference to innovator drug product literature	Batch No. DZ001, Mfg. Oct 2021, Expiry Oct 2023. • The firm submitted that we have performed studies against Dyson's own (as competitor) registered product Abeticholic Acid 10mg tablet, and as per that product complies with specifications.
3.2.P.5	• Justification shall be submitted for not including the test for water content in finished product specification as per innovator product review document • Justification shall be submitted for selecting the sampling time of 45min while dissolution specifications of NLT Q after 15min	• Revised specifications after including test for water content in FP specifications is submitted. • The firm submitted that it was a typographic error as our specifications are as per innovator's product specifications.
3.2.P.8	• Submit 6th month time point stability study data for the applied drug product • Submit documents for procurement of API with approval from DRAP • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• 6th month time point stability data for drug product is submitted. • Firm has submitted copy of commercial invoice for import of Obeticholic acid quantity 3kg by M/s Dyson Research Laboratories Lahore attested by AD (I&E) DRAP Lahore dated 24-09-2021. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.
Decision: Deferred for submission of following: • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **GMP certificate / GMP inspection report of applicant i.e. M/s CCL Pharmaceuticals conducted with in last three years** • **Pharmaceutical equivalence and CDP studies against the innovator/reference/comparator product**		

Case No# 02: Deferred Contract Manufacturing applications as per decision of 173rd meeting of Authority:

413.	Name, address of Applicant / Marketing Authorization Holder	M/s Asian Continental Pvt. Ltd., D-32, S.I.T.E. II, Super Highway, Karachi
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	**M/s Wimits Pharmaceuticals:** Firm has submitted copy of cGMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021 **M/s AsianContinental Pharmaceuticals:** Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-51/2004-Lic dated 07-02-2014 which specifies Tablet (General Human) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 31346 dated 02-11-2022
	Details of fee submitted	Rs.75,000/- dated 23-09-2022 (Deposit slip#94085008299)
	The proposed proprietary name / brand name	**Acvon 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate……10mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive acid blocker (P-CAB)
	Reference to Finished product specifications	In house specifications
	Proposed Pack size	1x10's, 2x10's, 2x7's, 3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda Pharmaceutical Company Limited, PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti Tablet 10mg by M/s The Searle Company Limited, (Reg. No. 108835)
	Name and address of API manufacturer.	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand that is Vonnp 10mg Tablet, by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the comparator product vonoprazan 10mg Tablet in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including linearity and range, accuracy, precision (Repeatability, Intermediate), specificity, robustness and system suitability.

STABILITY STUDY DATA			
Manufacturer of API	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China		
API Lot No.	TAK09-220101		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	VF001	VF002	VF003
Batch Size	100000 Tablets	100000 Tablets	100000 Tablets
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	18-06-2022	18-06-2022	18-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., Zhongshan Torch Hi-Tech IndustrialDevelopment Zone, Guangdong Province, China issued by Zhongshan Medical Association China valid upto 30-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

4.	Data of stability batches will besupported by attested respective document like chromatograms, Raw datasheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s AsianContinental Pvt Ltd
1.3.3	• You have mentioned that applicant is manufacturer while applicant is contract giver, clarify
1.3.5	• Submit GMP certificate / GMP inspection report of applicant conducted with in last three years
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Justification shall be submitted for using different chromatographic conditions (wavelength, injection volume, mobile phase) for assay test by drug product manufacturer than that by substance manufacturer • Justification shall be submitted for not performing the test for fumaric acid content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.

Applied product	**TAKECAB Tablets 10mg**
Vonoprazan Fumarate	Vonoprazan Fumarate
Lactose monohydrate, Mannitol, Avicel Ph 101, Klucel, Cross carmellose sodium, sodium starch glycolate, magnesium stearate, Tabcoat white, isopropyl alcohol, purified water	D-mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, yellow ferric oxide

	• Details of reference product including manufacturer, batch number, manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted • Details of comparator product including brand name, manufacturer, batch number, manufacturing and expiry date used in CDP studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies including the tests recommended by innovator product review document (uniformity of dosage units) • Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Justify the variation of dissolution parameters i.e. dissolution medium and time from that recommended by USFDA for the vonoprazan tablets. (use of phosphate buffer pH 6.8 instead of 0.05M acetate buffer pH 4.5, and Q at 30 minutes instead on Q at 15 minutes)
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Submit documents for procurement of API with approval from DRAP • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required

<table>
<tr><td></td><td>• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required</td></tr>
<tr><td colspan="2">Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings</td></tr>
<tr><td colspan="2">Response of the firm:</td></tr>
<tr><td colspan="2">
<table>
<tr><th>Section</th><th>Deferment Reason</th><th>Firm's Response</th></tr>
<tr><td>1.3.1</td><td>• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify?
• Cover letter and fee submitted is from M/s AsianContinental Pvt Ltd</td><td>• Firm has submitted details of applicant in Module 1 of Form 5F.
Applicant Details are:

M/s AsianContinental Pvt. Ltd., D-32, S.I.T.E. II, Super Highway, Karachi

• Documents submitted after Correction</td></tr>
<tr><td>1.3.3</td><td>• You have mentioned that applicant is manufacturer while applicant is contract giver, clarify</td><td>• The firm submitted that Applicant is a contract giver</td></tr>
<tr><td>1.3.5</td><td>• Submit GMP certificate / GMP inspection report of applicant conducted with in last three years</td><td>M/s AsianContinental Pharmaceuticals:

Firm has submitted copy of cGMP certificate dated 16-11-2022 based on inspection conducted on 27-09-2021.</td></tr>
<tr><td>1.6.5</td><td>• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required</td><td>The firm has submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China issued by Zhongshan Medical Association China valid upto 30-12-2023</td></tr>
<tr><td>3.2.S.4</td><td>• Justification shall be submitted for using different chromatographic conditions (wavelength, injection volume, mobilephase) for assay test by drug productmanufacturer than that by substance manufacturer
• Justification shall be submitted for not performing the test for fumaric acid content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer</td><td>• Firm has submitted revised Testing method of drug substance as per drug substance Manufacturer

• Fumaric acid content is performed and COA of drug product manufacturer is submitted</td></tr>
<tr><td>3.2.P.2</td><td>• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>TAKECAB Tablets 10mg</th></tr>
<tr><td>Vonoprazan Fumarate</td><td>Vonoprazan Fumarate</td></tr>
<tr><td>Lactose monohydrate, Mannitol, Avicel</td><td>D-mannitol, microcrystalline cellulose,</td></tr>
</table></td><td>• Compatibility studies of the drug substance(s) with excipients is submitted

• The details of Reference product
Brand Name: Voniza10mg tablet

Manufacturer: Hilton pharma

B.No.: 141102

MFG.: 11-2021 EXP:11-2023</td></tr>
</table>
</td></tr>
</table>

	Ph 101, Klucel, Cross carmellose sodium, sodium starch glycolate, magnesium stearate, Tabcoat white, isopropyl alcohol, purified water croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, yellow ferric oxide • Details of reference product including manufacturer, batch number, manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted • Details of comparator product including brand name, manufacturer, batch number, manufacturing and expiry date used in CDP studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies including the tests recommended by innovator product review document (uniformity of dosage units) • Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product	• Uniformity of dosage units is performed in the pharmaceutical equivalence studiesand submitted • The firm submitted that the innovator product is Takeda that is not easily available that why we use the local product which is easily available in the market.
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Justify the variation of dissolutionparameters i.e. dissolution medium and time from that recommended by USFDA for the vonoprazan tablets. (use of phosphate buffer pH 6.8 instead of 0.05M acetate buffer pH 4.5, and Q at 30 minutes instead on Q at 15 minutes)	• The firm has included the test for uniformity of dosage unit in finished product specifications • The firm submitted that we have considered PMDA Japan approved product as innovator wherein details of dissolution specifications have not been revealed hence we follow the general pharmacopeial guideline for dissolution specifications and parameters for immediate release tablets. Moreover the product approved by USFDA containing vonoprazan is a combo pack product while the applied product formulation is single unit tablet of vonprazan
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Submit documents for procurement of API with approval from DRAP • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Stability study data of applied product at 6th month time point is submitted. • Firm has submitted copy of Form 6 dated 27-05-2022 for import of 500g Vonoprazan fumarate in name of M/s Wimits Pharmaceuticals Pvt. Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 27-05-2022. *However copy of clearance certificate or ADC attested commercial invoice is not submitted. Furthermore the batch size is 100000 tablets while API imported is only 500gm.* • Compliance record of HPLC software 21CFR and audit trail reports on product is submitted. • Record of digital data logger of temperature and humidity monitoring of

		stability chambers (real time and accelerated) is submitted.

Decision: Deferred for submission of following:

- **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Reconciliation of the drug substance imported against the stability batches of drug product manufactured since batch size of applied product is 100,000 tablets (3 batches) while only 500gm of API imported.**

414.	Name, address of Applicant / Marketing Authorization Holder	M/s Asian Continental Pvt. Ltd., D-32, S.I.T.E. II, Super Highway, Karachi
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals Pvt. Ltd., Plot No# 129, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	**M/s Wimits Pharmaceuticals:** Firm has submitted copy of cGMP certificate dated 08-09-2021 based on inspection conducted on 08-09-2021 **M/s AsianContinental Pharmaceuticals:** Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-51/2004-Lic dated 07-02-2014 which specifies Tablet (General Human) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 31344 dated 02-11-2022
	Details of fee submitted	Rs.75,000/- dated 23-09-2022 (Deposit slip#4040398176)
	The proposed proprietary name / brand name	**Acvon 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate……20mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive acid blocker (P-CAB)
	Reference to Finished product specifications	In house specifications
	Proposed Pack size	1x10's, 2x10's, 2x7's, 3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 20mg tablet by M/s Takeda Pharmaceutical Company Limited, PMDA Japan Approved.

	For generic drugs (me-too status)	Vocinti Tablet 20mg by M/s The Searle Company Limited, (Reg. No. 108836)
	Name and address of API manufacturer.	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand that is Vonnp 20mg Tablet, by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the comparator product vonoprazan 20mg Tablet in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including linearity and range, accuracy, precision (Repeatability, Intermediate), specificity, robustness and system suitability.
STABILITY STUDY DATA		

Manufacturer of API	M/s Enantiotech Corporation Limited., No.6 Zhongjing RD, Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China		
API Lot No.	TAK09-220101		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	VM001	VM002	VM003
Batch Size	100000 Tablets	100000 Tablets	100000 Tablets
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	25-06-2022	27-06-2022	29-06-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., Zhongshan Torch Hi-Tech IndustrialDevelopment Zone, Guangdong Province, China issued by Zhongshan Medical Association China valid upto 30-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will besupported by attested respective document like chromatograms, Raw datasheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s AsianContinental Pvt Ltd
1.3.3	• You have mentioned that applicant is manufacturer while applicant is contract giver, clarify
1.3.5	• Submit GMP certificate / GMP inspection report of applicant conducted with in last three years
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required

3.2.S.4	• Justification shall be submitted for using different chromatographic conditions (wavelength, injection volume, mobile phase) for assay test by drug product manufacturer than that by substance manufacturer • Justification shall be submitted for not performing the test for fumaric acid content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.

Applied product	**TAKECAB Tablets 10mg**
Vonoprazan Fumarate	Vonoprazan Fumarate
Lactose monohydrate, Mannitol, Avicel Ph 101, Klucel, Cross carmellose sodium, sodium starch glycolate, magnesium stearate, Tabcoat white, isopropyl alcohol, purified water	D-mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, red ferric oxide

	• Details of reference product including manufacturer, batch number, manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted • Details of comparator product including brand name, manufacturer, batch number, manufacturing and expiry date used in CDP studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies including the tests recommended by innovator product review document (uniformity of dosage units) • Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product
3.2.P.5	• Justify the variation of dissolution parameters i.e. dissolution medium and time from that recommended by USFDA for the vonoprazan tablets. (use of phosphate buffer pH 6.8 instead of 0.05M acetate buffer pH 4.5, and Q at 30 minutes instead on Q at 15 minutes)
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Submit documents for procurement of API with approval from DRAP • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the firm:

Section	**Deferment Reason**	**Firm's Response**
1.3.1	• Submitted application is for contract manufacturing while details of applicant and manufacturer provided in module 1 of form 5F is same clarify? • Cover letter and fee submitted is from M/s AsianContinental Pvt Ltd	• Firm has submitted details of applicant in module 1 of Form 5F. Applicant Details are: M/s AsianContinental Pvt. Ltd., D-32, S.I.T.E. II, Super Highway, Karachi • Documents submitted after Correction
1.3.3	• You have mentioned that applicant is manufacturer while applicant is contract giver, clarify	• The firm submitted that Applicant is a contract giver
1.3.5	• Submit GMP certificate / GMP inspection report of applicant conducted with in last three years	M/s AsianContinental Pharmaceuticals: Firm has submitted copy of cGMP certificate dated 16-11-2022 based on inspection conducted on 27-09-2021.

<table>
<tr><td>1.6.5</td><td>• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required</td><td>The firm has submitted copy of cGMP certificate of M/s Enantiotech Corporation Limited., Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China issued by Zhongshan Medical Association China valid upto 30-12-2023</td></tr>
<tr><td>3.2.S.4</td><td>• Justification shall be submitted for using different chromatographic conditions (wavelength, injection volume, mobile phase) for assay test by drug product manufacturer than that by substance manufacturer
• Justification shall be submitted for not performing the test for fumaric acid content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer</td><td>• Firm has submitted revised Testing method of drug substance as per drug substance Manufacturer
• Fumaric acid content is performed and COA of drug product manufacturer is submitted</td></tr>
<tr><td>3.2.P.2</td><td>• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>TAKECAB Tablets 10mg</th></tr>
<tr><td>Vonoprazan Fumarate</td><td>Vonoprazan Fumarate</td></tr>
<tr><td>Lactose monohydrate, Mannitol, Avicel Ph 101, Klucel, Cross carmellose sodium, sodium starch glycolate, magnesium stearate, Tabcoat white, isopropyl alcohol, purified water</td><td>D-mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, red ferric oxide</td></tr>
</table>
• Details of reference product including manufacturer, batch number, manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted
• Details of comparator product including brand name, manufacturer, batch number, manufacturing and expiry date used in CDP studies shall be submitted
• Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies including the tests recommended by innovator product review document (uniformity of dosage units)
• Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product</td><td>• Compatibility studies of the drug substance(s) with excipients is submitted
• The details of Reference product
Brand Name: Voniza 20mg tablet
Manufacturer: Hilton pharma
B.No.: 141606
MFG.: 12-2021 EXP:12-2023
• Uniformity of dosage units is performed in the pharmaceutical equivalence studies and submitted
• The firm submitted that the innovator product is Takeda that is not easily available that why we use the local product which is easily available in the market.</td></tr>
</table>

3.2.P.5	• Justify the variation of dissolution parameters i.e. dissolution medium and time from that recommended by USFDA for the vonoprazan tablets. (use of phosphate buffer pH 6.8 instead of 0.05M acetate buffer pH 4.5, and Q at 30 minutes instead on Q at 15 minutes)	• The firm has included the test for uniformity of dosage unit in finished product specifications • The firm submitted that we have considered PMDA Japan approved product as innovator wherein details of dissolution specifications have not been revealed hence we follow the general pharmacopeial guideline for dissolution specifications and parameters for immediate release tablets. Moreover the product approved by USFDA containing vonoprazan is a combo pack product while the applied product formulation is single unit tablet of vonprazan
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Submit documents for procurement of API with approval from DRAP • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Stability study data of applied product at 6th month time point is submitted. • Firm has submitted copy of Form 6 dated 27-05-2022 for import of 500g Vonoprazan fumarate in name of M/s Wimits Pharmaceuticals Pvt. Ltd., Lahore attested by AD (I&E) DRAP Lahore dated 27-05-2022. *However copy of clearance certificate or ADC attested commercial invoice is not submitted. Furthermore the batch size is 100000 tablets while API imported is only 500gm.* • Compliance record of HPLC software 21CFR and audit trail reports on product is submitted. • Record of digital data logger of temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.
Decision: Deferred for submission of following: • **Fee of Rs. 75,000/- for change of Applicant / Marketing Authorization Holder, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin** • **Reconciliation of the drug substance imported against the stability batches of drug product manufactured since batch size of applied product is 100,000 tablets (3 batches) while only 500gm of API imported.**		

Case No. 03; Deferred Registration application of Human drugs on Form 5-F on export facilitation

415.	Name, address of Applicant / Marketing Authorization Holder	Surge Laboratories (Pvt.) Ltd., 10th Km, Faisalabad road, Bikhi District, Sheikhupura Pakistan
	Name, address of Manufacturing site.	Surge Laboratories (Pvt.) Ltd., 10th Km, Faisalabad road, Bikhi District, Sheikhupura Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 05-04-2022 based on inspection conducted on 05-10-2021

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-18/95-Lic (Vol-III) dated 11-01-2022 which specifies Dry powder injectable (cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25815 dated 13-09-2022
	Details of fee submitted	Rs.30,000/- dated 27-07-2022 (Deposit slip#38543763329)
	The proposed proprietary name / brand name	XTRAZID-AV 2g/0.5g Powder for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime pentahydrate eq. to Ceftazidime… .....2g Avibactam sodium eq. to avibactam..... 0.5g
	Pharmaceutical form of applied drug	Intravenous infusion
	Pharmacotherapeutic Group of (API)	Ceftazidime belongs to the group of antibiotics called “cephalosporin” Avibactam is “beta-lactamase inhibitor”
	Reference to Finished product specifications	Innovators Specs.
	Proposed Pack size	20ml vial of sterile dry for injection + 1 ampoule of 10ml Sterile Water for Injection to make 12ml clear solution in a single pack
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion MHRA Approved Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion TGA Approved AVYCAZ (ceftazidime/avibactam) 2g/0.5g for injection USFDA Approved
	For generic drugs (me-too status)	Zavicefta Injection 2g/0.5g (Powder for Concentrate for Solution for Infusion) by M/s Pfizer Pakistan Ltd (Reg#106848)
	Name and address of API manufacturer.	M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (180601, 180602, 180603)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Zavicefta 2g/0.5g Powder for solution for infusion IV by M/s Pfizer Limited., by performing quality tests (Description, pH, Sterility test and Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, system suitability, robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China		
API Lot No.	2105001		
Description of Pack (Container closure system)	20ml clear glass vial tubular USP Type-I		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CFA-2.5-001	CFA-2.5-002	CFA-2.5-003
Batch Size	15 vials	15 vials	15 vials
Manufacturing Date	17-8-2021	24-9-2021	24-9-2021
Date of Initiation	10-2022	10-2022	10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, China issued by

		China Food and Drug Administration valid upto 21-02-2022. Firm has also submitted copy of DML (certificate No#Nei20160028) in in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, China valid upto 27-12-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 17-06-2021 for import of 300gm of Avibactam and Ceftazidim sterile (Batch#2105001) in name of M/s Surge Laboratories (Pvt) Ltd attested by AD (I&E) DRAP Lahore dated 09-07-2021. Firm has also submitted copy of form 6 dated 09-07-2021 for import of 300gm of Avibactam and Ceftazidim sterile powder (1:4) in name of M/s Surge Laboratories (Pvt) Ltd attested by AD (I&E) DRAP Lahore dated 09-07-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Manual data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]: Letters of deficiency sent on 19th May 2023 and reminder on 25th August 2023 but no reply received

Section	Observations
1.5.10	• Clearly mention the dosage form of applied drug
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Justification shall be submitted for the dispensed quantity of drug substance against the label claim with reference to the potency of drug substance determined during drug substance analysis by M/s Surge Laboratories. • Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance are different than that recommended by innovator product
3.2.S.4	• Justification is required for using different chromatographic conditions i.e. mobile phase composition (buffer: acetonitrile; 50;50), injection volume (20ul), isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance • Justification is required for using different chromatographic conditions i.e. mobile phase composition, injection volume (20ul), flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance • Justification is required for not performing the test for reconstitutions, content uniformity, pyridine content, particulate matter, bacterial endotoxin and sterility in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer
3.2.P.1	• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.

3.2.P.2	• Justification is required since pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, identification, pyridine content, uniformity of dosage unit, particulate matter, water content, and bacterial endotoxins
3.2.P.5	• Justification is required for not including the test for pyridine content and water content in finished product specification by drug product manufacturer as recommended by innovator product review document • The limits of pH test for drug substance by drug product manufacturer was 5.5-7.5 while limits of pH test for drug product by drug product manufacturer was 5-7.5, clarify • Justification is required for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document
3.2.P.8	• Justification is required for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document • Clarification is required as you have mentioned the manufacturing date of trial batches CFA-2.5-002 and CFA-2.5-003 as august instead of October in in-use stability study

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of firm:

Section	Deferment Reason	Response of Firm
1.5.10	• Clearly mention the dosage form of applied drug	• Corrected dosage form according to innovator literature as Intravenous injection in section 1.5.10.
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	• The firm submitted that after the amendment of the Drug Administration Law (DAL) of the People's Republic of China, the requirement for GMP has been abolished, and China no longer issues GMP certificates. The declaration by the National Medical Drugs Administration is submitted • Firm has also submitted copy DML# 20160028 of M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China valid upto 27-12-2025
2.3.R.1	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life	• The firm submitted that Ceftazidime 2.0gm + Avibactam 0.5gm sterile ready-to-fill pre-mixed powder material provided by manufacturer to be filled in aseptic conditions and no formulation and manufacturing procedure (instead of aseptic filling) is involved, on the basis of this risk assessment we can rely on the stability studies (attached) provided by the manufacturer according to ICH Zone IVA conditions. • On the basis of above declaration, we have designed trials quantity as minimum as possible to do the necessary testing/studies. However, we commit to provide complete testing of Finished product till shelf life for commercial batches. • Three batches each of 15 vials were prepared to conduct testing upto 06 months for stability

		studies on the above mentioned rationale with necessary test studies. • Justification letter and Undertaking is submitted
	• Justification shall be submitted for the dispensed quantity of drug substance against the label claim with reference to the potency of drug substance determined during drug substance analysis by M/s Surge Laboratories.	• The firm submitted that as per manufacturerCOA of drug substance % potency of Ceftazidime as pentahydrate is 64.80% and Avibactum as sodium is 16.80% while on testing by Drug product manufacturer results obtained for Ceftazidime pentahydrate is 60.99% and Avibactum as sodium is 15.75% on as is basis. So the dispensed quantity of drug substance taken is 49.185gm/batch by considering 60.99% assay. • **<u>Calculation of proposed weight on the basis of Ceftazidime potency:</u>** Assay of Ceftazidime (On as is basis) = 60.99% Fill weight = label claim x 100/ Assay % (on as such basis) =2000x100/60.99 = 3279mg/vial • **<u>Calculation of proposed weight on the basis of Avibactum potency</u>** Assay of Avibactum on as is basis = 15.75% Fill weight = label claim x 100/ Assay % (on as such basis) =500 x 100/15.75 = 3174mg/vial • Fill weight of Ceftazidime + Avibactum injection has been selected 3279mg/vial to calculate the batch size which is maximum of both and have both API > 100%. • Justification letter is submitted
	• Justification shall be submitted asthe content of sodium bicarbonate in premixed drug substance are different than that recommended by innovator product	• Content of Sodium bi carbonate in premixed drug substance are not different as recommended by innovator product. Justification letter for the same is submitted**.**
3.2.S.4	• Justification is required for using different chromatographic conditions i.e. mobile phase composition (buffer: acetonitrile; 50;50), injection volume (20ul), isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance • Justification is required for using different chromatographic conditions i.e. mobile phase composition, injection volume (20ul), flow rate than that recommended by drug substance	• The firm submitted that we have done analytical method validation on our In-House method as per ICH Q2(R1) guidelines use in API testing. Since the API is non–compendia so our In-House validated method is also applicable for testing of API • Changes are made due to better elution of both API's. • Justification letter is submitted

	manufacturer for assay of ceftazidime drug substance	
	• Justification is required for not performing the test for reconstitutions, content uniformity, pyridine content, particulate matter, bacterial endotoxin and sterility in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer	• The firm submitted that test for particulate matter, bacterial endotoxin and sterility were performed on API but not reported in chemical test results. In-House COA as separate reports were generated by microbiology department which are submitted. • However, since this material was sterile ready to fill material and no addition of excipients or formulation has been carried at our site, so tests for content uniformity and pyridine content were performed on finished product testing. At API testing stage these tests were taken from API manufacturer COA. • Revise API COA is submitted.
3.2.P.1	• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.	• The powder for Injection Ceftazidime 2gm+Avibactam 0.5gm is required to be reconstituted with 10ml of Water For Injection prior to mix with intravenous infusion. • **Type of Diluent Used for Reconstitution:** Water For Injection 10ml Filled in 10ml glass ampoule USP Type-I. • **Composition:** Each 10ml ampoule contains 10ml of Sterilized Water For Injection [BP Specs.] • **Regulatory Status in Pakistan:** This diluent (Water for Injection 10ml) having Drug Registration Number:026762 which will be provided with the applied drug product for registration.
3.2.P.2	• Justification is required since pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, identification, pyridine content, uniformity of dosage unit, particulate matter, water content, and bacterial endotoxins	• The firm submitted that we have again conducted pharmaceutical equivalence studies including complete testing of drug product manufactured by us and the innovator product. • Updated Pharmaceutical Equivalence studies with complete testing is submitted
3.2.P.5	• Justification is required for not including the test for pyridine content and water content in finished product specification by drug product manufacturer as recommended by innovator product review document	• The firm submitted that we have previously revised Finished Product Specifications mentioning all test as per innovator product review document including test for pyridine content and water content. • Updated Finished Product Specifications are submitted**.**
	• The limits of pH test for drug substance by drug product manufacturer was 5.5-7.5 while limits of pH test for drug product by	• The firm submitted that the limits of pH for drug substance by API manufacturer was 5.5 – 7.5, while we have mentioned pH range 5.0 – 7.5 in submitted product specifications. It was a

<table>
<tr><td></td><td>drug substance manufacturer was 5-7.5, clarify</td><td>typographical error while compiling product specifications. The pH range 5.5 – 7.5 is the actual and all of our pH results provided in the submitted documents are in the range of 5.5 - 7.5. We have made necessary corrections in the specifications and related documents.

• pH Data of All Trial Batches of Ceftazidime 2gm + Avibactam 0.5gm Injection and Reference Product is given below:<table><tr><td>Batch</td><td>Results</td></tr><tr><td>Innovator Batch</td><td>6.46</td></tr><tr><td>Trial Batch CFA-2.5-001</td><td>6.45</td></tr><tr><td>Trial Batch CFA-2.5-002</td><td>6.60</td></tr><tr><td>Trial Batch CFA-2.5-003</td><td>6.51</td></tr><tr><td>Trial Batch CFA-2.5-004</td><td>6.72</td></tr></table>• Above data shows that pH of the trial samples and innovator sample is comparable and well within the range (5.5 – 7.5).</td></tr>
<tr><td></td><td>• Justification is required for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document</td><td>• The firm submitted that we have manufactured another trial batch, Batch No: CFA-2.5-004 and complete testing was performed on said batch.
• COA of said batch and justification letter is submitted.</td></tr>
<tr><td>3.2.P.8</td><td>• Justification is required for not performing the test for description on reconstitution, reconstitutions time, pyridine content, watercontent, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document
• Clarification is required as you have mentioned the manufacturing date of trial batches CFA-2.5-002 and CFA-2.5-003 as august instead of October in in-use stability study</td><td>• Same justification letter as above.
• The firm submitted that manufacturing date of trial batches CFA-2.5-002 and CFA-2.5-003 was September 2021. Date mention on the report of In-Use stability studies as August is a typo- error. Corrected document /report is submitted</td></tr>
<tr><td colspan="3">Decision: Deferred for submission of following:
• Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
• Justification of the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life
• Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance
• Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance
• Justification for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial</td></tr>
</table>

endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document.

- **Justification for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document**

Case No. 04: Deferred Registration Application of Human Drugs on form 5F (import)

416.	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:** 05-352-0058-066904D **Address:** 2nd Floor, Plaza 60, Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24-02-2023. **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	Hainan Brilliant Pharmaceutical Co., Ltd., 4 Medicine Valley, No. 1 Road, Haikou National High-tech Development Zone, Haikou City, China.
	Name, address of manufacturer(s)	Hainan Brilliant Pharmaceutical Co., Ltd., No. 4 Fist Road of Yaogu, Haikou National High-tech Industrial Development Zone, Haikou City, Hainan Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 20210060) dated 16-04-2021 issued by Hainan Provincial Medical Products Administration China for azithromycin for injection 0.5g. The CoPP confirms that the product strength is not in market of 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 15-04-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of agency agreement from M/s Hainan Brilliant Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Lahore** to register their products in Pakistan. The authorization letter is valid till 22-10-2024. The letter issued for azithromycin for injection 500mg.
	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. 26416: 23-09-2021
	Details of fee submitted	PKR 150,000/-: 29-06-2021 (Slip#306286776760)
	The proposed proprietary name / brand name	**ZITHROBAR INJECTION 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Active ingredient Name; Azithromycin Strength; 500mg
	Pharmaceutical form of applied drug	Powder for injection (Lyophillized)
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Macrolides
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	Rs 215/-
	The status in reference regulatory authorities	ZITHROMAX 500mg for injection USFDA Approved.
	For generic drugs (me-too status)	Azineu 500mg Injection by M/s Neutro Pharma (Reg# 097656)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Zhejiang Goubang Pharmaceutical Co., Ltd., No.6, Weiwu Road, Hangzhou Gulf Shangyu Economic & Technological Development Zone, Zhejiang 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 (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 30 ºC ± 2ºC / 75 ± 5% RH for 24 months while accelerated stability study is

		conducted at 40 ºC ± 2ºC / 75 ± 5% RH for 06 months. Batch No# (103-180306-11, 103-180307-11, 103-180308-11)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence against the innovator product Zithromax 500mg Inj by performing quality test (pH, Water Content, Bacterial Endotoxin, Sterility, Visible particle, Assay).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Injection Vial made of Middle Borosilicate Glass tubing (10ml) with brominated rubber stopper and caps made of aluminium-polypropylene combinations
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. ***The real time stability study data is submitted for 18 months only.***

Batch No.	**Mfg. date**	**Batch size**
1905051	05.05.2019	5000 vials
1905091	09.05.2019	5000 vials
1905131	13.05.2019	5000 vials

Remarks of Evaluator [XI]:

Section	**Observations**	**Response**
1.3.3	The submitted CoPP confirms that the product strength is not in market of exporting country, clarify?	The firm submitted clarification from Director Quality Department, Hainan Brilliant Pharmaceutical Co., Ltd and stated that the azithromycin for injection 0.5g has been marketed in China (Exporting Country). The person responsible for the application of CoPP misunderstood the exporting country was referring to Pakistan thus ticked wrong column in CoPP.
1.5.2	Strength of Active ingredient shall be stated clearly. In case API is in the form of salt / hydrate, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.	The firm have submitted the label claim as: Each vial contains: Azithromycin as dihydrate…….500mg
1.5.15-1.5.20	Commitments must be submitted by applicant (marketing authorization Holder) instead of manufacturer	The firm has submitted commitments as per guidance document

1.6.5	Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm has submitted GMP certificate No. ZJ20190170 in the name of M/s Zhejiang Goubang Pharmaceutical Co., Ltd., No.6, Weiwu Road, Hangzhou Gulf Shangyu Economic & Technological Development Zone, Zhejiang China valid upto 29/11/2024
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer and drug product manufacturer is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Copies of the analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drugsubstance manufacturer and drug product manufacturer is submitted. • Analytical Method Verification studies including specificity, linearity range, precision, accuracy, solution stability and robustness performed by the Drug Product manufacturer for drug substance(s) is submitted.
3.2.P.5	• You have applied for USP specifications. However, the limits for assay test given in specifications is not according to USP monograph, clarify? ***Release specifications; (103%-113%)*** ***Shelf life specifications; (101%-115%)*** ***Monograph: (90%-110%)*** • Test for uniformity of dosage units is not included in specifications recommended by USP • The chromatographic conditions of the analytical method are different from the USP monograph (mobile phase, injection volume, lambda,	The firm submitted that specification applied for azithromycin for injection 0.5g is in-house specification rather than USP, so there is difference in specification, test items and chromatographic conditions compared to USP.
3.2.P.8	• Submit stability study data of drug product till the claimed shelf life	The firm have submitted stability study data of three batches. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH for 24 months

Previous Decision (321-DRB): Deferred for following points:

- Clarification for not complying USP specifications of finished drug product as USP specifications are more stringent to in-house specifications.
- Whether manufacturing has been done via lyophilization or dry powder filling and relevant manufacturing facility thereof.

Evaluation by PEC:

- The firm has submitted USP specifications for the applied product. The firm has also submitted commitment to provide product according to USP specifications.
- The firm submitted that manufacturing has been done by method of lyophilisation and submitted inspection report for relevant section of manufacturer. The firm has also submitted cGMP certificate No#HI20190027 in name of M/s Hainan Brilliant Pharmaceutical Co., Ltd., 4 Medicine Valley, No. 1 Road, Haikou National High-tech Development Zone, Haikou City, China for lyophilized powder for injection valid upto 28-05-2024

Previous Decision (M-322-DRB): Deferred for following:

- Clarification since the Chinese Pharmacopeia doesnot include the test for quantification of impurity E as recommended by USP monograph
- Clarification since the limits of assay test given in Chinese Pharmcoapeia i.e. 101-115% is different than that recommended by USP i.e. 90-110%.

Response of firm:

Deferrement Reason	Firm's Response
• Clarification since the limits of assay test given in Chinese Pharmcoapeia i.e. 101-115% is different than that recommended by USP i.e. 90-110%.	• The firm submitted that assay results of 30 batches of Azithromycin for Injection marketed in China (Exportin Country) are analyzed to compare the batch-to-batch assay difference, and the results show that all the assay results of 30 batches are within range of 105% to 108%, and most of batches are kept within the range of 106% to 107%. • In conclusion, it is estimated that the assay of final drug product produced by M/s Brilliant Pharma can comply with USP requirements of NLT 90.0% and NMT 110.0%.
• Clarification since the Chinese Pharmacopeia doesnot include the test for quantification of impurity E as recommended by USP monograph	• Impurity E difference in USP and ChP, primarily is due to difference in analytical methods employed. A table (attached) shows comparison between ChP and USP demonstrates that apparently Chinese Pharmacopeia is stringet than USP. Moreover Hainan Brilliant commits to provide product Azithromycin 500mg according to USP. Commitment letter is submitted
Decision: Appropved. The company will Submit original valid legalized COPP of applied drug product issued by relevant regulatory authority of country of origin.	

Agenda of Evaluator PEC-XV

Cases of New DML received on Form 5-F

417.	Name, address of Applicant / Marketing Authorization Holder	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24778 dated 11-10-2023
	Details of fee submitted	Rs.30,000/- dated 07-09-2023
	The proposed proprietary name / brand name	CARAMIC 250mg Capsules.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Tranexamic acid..... 250mg. (JP Specs)

	Pharmacotherapeutic Group of (API)	Antifibrinolytics
	Pharmaceutical form of applied drug	White to off white powder filled in white red capsules
	Reference to Finished product specifications	(JP Specs)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Hexatron capsule 250mg PDMA Japan Approved.
	For generic drugs (me-too status)	M/s Hilton Pharma (Pvt) Ltd. Karachi. Transamine 250mg/capsule Reg. NO. 006524
	Name and address of API manufacturer.	Changzhou Yinsheng Pharmaceutical Co., Ltd. Manufacturing site address: Weitang Chemical Zone, Xinbei District, Changzhou, Jiangsu Province, 213033, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP studies of their product against the Transamin 250mg capsule
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Changzhou Yinsheng Pharmaceutical Co., Ltd. Manufacturing site address: Weitang Chemical Zone, Xinbei District, Changzhou, Jiangsu Province, 213033, China		
API Lot No.	2112006		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1300 Capsules	1300 Capsules	1300 Capsules
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. JS20170680) valid till 20-06-2022 issued by Jiangsu Food And Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
1.6.5	Valid GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.S.5	COA of working standard used for analysis of drug substance shall be submitted.	Submitted
3.2.P.8.3	Documents confirming import of drug substance , with approval of DRAP shall be submitted.	Submitted
2.3.R.1.1	Submit complete batch manufacturing record of three stability batches.	Submitted

Decision: Approved.

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

418.	Name, address of Applicant / Marketing Authorization Holder	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24305 dated 11-10-2023
	Details of fee submitted	Rs.30,000/- dated 07-09-2023
	The proposed proprietary name / brand name	Caramic 500mg/5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml ampoule contain: Tranexamic acid..... 500mg.
	Pharmacotherapeutic Group of (API)	Antifibrinolytics
	Pharmaceutical form of applied drug	Clear solution free from particulate matter filled in transparent ampule
	Reference to Finished product specifications	(USP Specs)
	Proposed Pack size	5's,10's in PVC Tray
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	M/s Hilton Pharma (Pvt) Ltd. Karachi.Transamine 500mg/capsule Reg. NO. 005024
	Name and address of API manufacturer.	Changzhou Yinsheng Pharmaceutical Co., Ltd. Manufacturing site address: Weitang Chemical Zone, Xinbei District, Changzhou, Jiangsu Province, 213033, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process

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

STABILITY STUDY DATA			
Manufacturer of API	Changzhou Yinsheng Pharmaceutical Co., Ltd. Manufacturing site address: Weitang Chemical Zone, Xinbei District, Changzhou, Jiangsu Province, 213033, China		
API Lot No.	2112006		
Description of Pack (Container closure system)	5's,10's in PVC Tray		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	• N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. JS20170680) valid till 20-06-2022 issued by Jiangsu Food And Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--

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

Remarks of Evaluator:

Section no.	Observation	Firm's response
1.6.5	Valid GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.S.5	COA of working standard used for analysis of drug substance shall be submitted.	Submitted
3.2.P.8.3	Documents confirming import of drug substance , with approval of DRAP shall be submitted.	Submitted
2.3.R.1.1	Submit complete batch manufacturing record of three stability batches.	Submitted

Decision: Approved.

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

419.	Name, address of Applicant / Marketing Authorization Holder	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 22950 dated 19-09-2023
	Details of fee submitted	Rs.30,000/- dated 07-09-2023
	The proposed proprietary name / brand name	FUNGI-CARE 150mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluconazole..... 150mg.
	Pharmacotherapeutic Group of (API)	ANTIFUNGAL

	Pharmaceutical form of applied drug	White to off white powder filled in Blue/white capsules
	Reference to Finished product specifications	(BP Specs)
	Proposed Pack size	1'ss Capsule.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azocan150mg MHRA Approved.
	For generic drugs (me-too status)	Diflucan 150mg/capsule M/s Pfizer Pakistan Ltd. Reg. NO. 011828
	Name and address of API manufacturer.	HEMA Pharmaceutical Pvt. LTD. Plot No.:-6201/A&B, GIDC ESTATE, Opp. EWAC ALLOY LTD, ANKLESHWAR-393002.GUJARAT-INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Diflucan 150mg Capsule by Pfizer Pakistan along with CDP studies in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	HEMA Pharmaceutical Pvt. LTD. Plot No.:-6201/A&B, GIDC ESTATE, Opp. EWAC ALLOY LTD, ANKLESHWAR-393002.GUJARAT-INDIA.		
API Lot No.	FLP117122111		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate no. 21012394 issued by Food & Drug Control Administration, Gujarat State valid till 04-01-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared specifying 1Kg of Tranexamic acid The invoice is cleared by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
3.2.S.4.3	Analytical method verification studies of drug substance performed by M/s Carer Pharma shall be submitted.	Submitted
3.2.P.3.2	Performance of accuracy parameter shall be submitted in drug product analytical method verification studies.	Submitted
2.3.R.1.1	Submit complete batch ,manufacturing record of three stability batches.	Submitted

Decision: Approved.

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

420.	Name, address of Applicant / Marketing	Carer Pharmaceuticals Industries. Plot NO 27 Main

	Authorization Holder	Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24306 dated 04-10-2023
	Details of fee submitted	Rs.30,000/- dated 07-09-2023
	The proposed proprietary name / brand name	Caramine Injection 30mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains Ketorolac Tromethamine ……. 30mg (USP Specs)
	Pharmacotherapeutic Group of (API)	ANTI-INFLAMMATORY, NON-STEROID
	Pharmaceutical form of applied drug	Colorless to pale yellowish, clear solution filled in clear glass ampoule.
	Reference to Finished product specifications	(USP Specs)
	Proposed Pack size	5’s, in PVC Tray
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ketorolac Tromethamin Injection, 30mg/ml Solution for injection MHRA approved.
	For generic drugs (me-too status)	M/s Martin Dow Marker Ltd. Toradol 30mg /1ml Reg. NO.108584
	Name and address of API manufacturer.	M/s. Satyadivis Pharmaceuticals Pvt. Ltd., Survey No. 10, Gaddapotaram (V), Khazipally I.D.A., Jinnaram (M), Sangareddy Dist.-502 319. T.S. INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form,

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

STABILITY STUDY DATA

Manufacturer of API	M/s. Satyadivis Pharmaceuticals Pvt. Ltd., Survey No. 10, Gaddapotaram (V), Khazipally I.D.A., Jinnaram (M), Sangareddy Dist.-502 319. T.S. INDIA.		
API Lot No.	0250522		
Description of Pack (Container closure system)	5's,10's in PVC Tray		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2000 Ampoules	2000 Ampoules	2000 Ampoules
Manufacturing Date	02-2023	02-2023	02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Last Product Caraprox 500mg tablets approved in 323 meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted License Retention Receipt for the renewal of DML issued by Drug Control Administration, Government of Telangana.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--

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

Remarks of Evaluator:

Section no.	Observation	Firm's response
3.2.P.8.3	Documents confirming import of drug substance , with approval of DRAP shall be submitted.	Submitted
2.3.R.1.1	Submit complete batch manufacturing record of three stability batches.	Submitted

Decision: Approved.

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

421.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26509 dated 02-11-2023
	Details of fee submitted	Rs 30,000/- dated 24-10-2023
	The proposed proprietary name / brand name	**CP-Derm 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine HCl equivalent to Terbinafine …… 250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	White round tablets
	Reference to Finished product specifications	USP specs.
	Proposed Pack size	10's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil® Tablets 250mg TGA Approved.
	For generic drugs (me-too status)	Terbiderm 250mg Tablets
	Name and address of API manufacturer.	SYNERGENE ACTIVE INGREDIENTS PVT LTD Unit-[,Plot No:59-D, Jawaharlal Nehru Pharma City, Parawada (V), Parawada Mandal, Vi sakhapatnam D i strict - 53 | 021, Andhra Prade sh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Lamisil® Tablets 250mg along with CDP studies in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	SYNERGENE ACTIVE INGREDIENTS PVT LTD Unit-[,Plot No:59-D, Jawaharlal Nehru Pharma City, Parawada (V), Parawada Mandal, Vi sakhapatnam D i strict - 53 | 021, Andhra Prade sh, India
API Lot No.	TBP107092211

Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	03-2023	03-2023	03-2023
No. of Batches	03		

422.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26511 dated 02-11-2023
	Details of fee submitted	Rs 30,000/- dated 24-10-2023
	The proposed proprietary name / brand name	**CP-Derm 125mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine HCl equivalent to Terbinafine …… 125mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	White round tablets
	Reference to Finished product specifications	USP specs.
	Proposed Pack size	10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil® Tablets 125mg TGA Approved.
	For generic drugs (me-too status)	Terbiderm 125mg Tablets Reg. NO. 032003
	Name and address of API manufacturer.	SYNERGENE ACTIVE INGREDIENTS PVT LTD Unit-[,Plot No:59-D, Jawaharlal Nehru Pharma City, Parawada (V), Parawada Mandal, Vi sakhapatnam D i strict - 53 | 021, Andhra Prade sh, India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Lamisil® Tablets 125mg along with CDP studies in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	SYNERGENE ACTIVE INGREDIENTS PVT LTD Unit-[,Plot No:59-D, Jawaharlal Nehru Pharma City, Parawada (V), Parawada Mandal, Vi sakhapatnam D i strict - 53 | 021, Andhra Prade sh, India
API Lot No.	TBP107092211
Description of Pack (Container closure system)	Alu-alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	04-04-2023	04-04-2023	04-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 5745,/P&B/2) dated 09-01-2020 issued by Food and Drugs Control Administration Gujrat State India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 01-12-2020 specifying 50Kg of Terbinafine HCl The invoice is cleared by AD (I&E) DRAP, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
3.2.S.4.3	Analytical method verification for drug substance shall be submitted from M/s Carer Pharma	Submitted
3.2.P.6	COA of working standard used for analysis of drug product stability batches shall be submitted.	Submitted

Decision: Registration board approved the applications of CP-Derm 250mg Tablet & CP-Derm 125mg Tablet Approved.

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

423.	Name, address of Applicant / Marketing Authorization Holder	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-

		Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26510 dated 02-11-2023
	Details of fee submitted	Rs 30,000/- dated 24-10-2023
	The proposed proprietary name / brand name	**CINMYOR 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Clarithromycin 500mg
	Pharmacotherapeutic Group of (API)	Antibiotic(Macrolides)
	Pharmaceutical form of applied drug	white color, oblong shaped Film coated tablets
	Reference to Finished product specifications	USP specs.
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 250mg tablets MHRA Approved.
	For generic drugs (me-too status)	Klaricid 250mg tablets Reg. NO. 013149
	Name and address of API manufacturer.	Nexchem Pharmaceutical Co., Ltd. Add: No. 1318 Jinsha Street Linjiang Industrial Zone, Wucheng District, Jinhua City, Zhejiang, 321025 P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Clarithromycin 250mg tablets manufactured by Sandoz S.R.L., Livezeni Street no. 7A, RO-540472, Targu Mures, Romania Sandoz GmbH, Biochemiestraße 10, 6050 Kundl, Austria Firm has submitted CDP results of their product against the innovator's product Klaricid 250mg tablets in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Nexchem Pharmaceutical Co., Ltd. Add: No. 1318 Jinsha Street Linjiang Industrial Zone, Wucheng District, Jinhua City, Zhejiang, 321025 P.R. China		
API Lot No.	2202-5091-FP004		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03/2023	03/2023	03/2023
No. of Batches	03		

424.	Name, address of Applicant / Marketing Authorization Holder	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021 and
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26509 dated 02-11-2023
	Details of fee submitted	Rs 30,000/- dated 24-10-2023
	The proposed proprietary name / brand name	**CINMYOR 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Clarithromycin 250mg
	Pharmacotherapeutic Group of (API)	Antibiotic(Macrolides)
	Pharmaceutical form of applied drug	white color, oblong shaped Film coated tablets
	Reference to Finished product specifications	USP specs.
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 250mg tablets MHRA Approved.
	For generic drugs (me-too status)	Klaricid 250mg tablets Reg. NO. 013149
	Name and address of API manufacturer.	Nexchem Pharmaceutical Co., Ltd. Add: No. 1318 Jinsha Street Linjiang Industrial Zone, Wucheng District, Jinhua City, Zhejiang, 321025 P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Clarithromycin 250mg tablets manufactured by Sandoz S.R.L., Livezeni Street no. 7A, RO-540472, Targu Mures, Romania Sandoz GmbH, Biochemiestraße 10, 6050 Kundl, Austria Firm has submitted CDP results of their product against the innovator's product Klaricid 250mg tablets in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Nexchem Pharmaceutical Co., Ltd. Add: No. 1318 Jinsha Street Linjiang Industrial Zone, Wucheng District, Jinhua City, Zhejiang, 321025 P.R. China		
API Lot No.	2202-5091-FP004		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03/2023	03/2023	03/2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. ZJ20160068) dated 06-06-2021 DML NO ZHE20000399 dated 05-11-2020 issued by Food and Drugs Control Administration Zhejiang China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not CFR Compliance submitted raw data sheets and spectrums provided.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		

	Section no.	Observation	Firm's response	
	1.6.5	Valid GMP certificate of drug substance manufacturer shall be submitted.	Submitted	
	3.2.S.4.4	COA of relevant batch of drug substance used for manufacturing of drug product trial batches, shall be submitted.	Submitted	
	3.2.P.5.3	Performance of accuracy parameter shall be submitted in drug product analytical method verification studies.	Submitted	

Decision: Registration Board approved the applications of CINMYOR 500mg Tablet & CINMYOR 250mg Tablet.

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

425.	Name, address of Applicant / Marketing Authorization Holder	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Name, address of Manufacturing site.	Carer Pharmaceuticals Industries. Plot NO 27 Main Road Industrial Estate Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 07/06/2021
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic. dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Application No. 477 dated 29-11-2023
	Details of fee submitted	Rs.30,000/- challan no. 16735639 dated 14-11-2023
	The proposed proprietary name / brand name	**CareInject Injection 50 mg Iron/ml; 10 ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule of 10 mL contains: Ferric carboxymaltose corresponding to iron. 500mg
	Pharmacotherapeutic Group of (API)	Anti-Anemic
	Pharmaceutical form of applied drug	Liquid Dispersion for Injection/Infusion
	Reference to Finished product specifications	Innovator product
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Injectafer Injection 500mg Iron /10ml (USFDA Approved)
	For generic drugs (me-too status)	Ferinject Injection (Each 10ml vial contains: Iron as Ferric carboxymaltose 500mg) of M/s. RG Pharmaceutical Reg.no. 072548.

	Name and address of API manufacturer.	Nanjing Hencer Pharmaceutical Co., Ltd No. 18 Jichang Road, Lishui Economic & Technological Development Zone, Nanjing City, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report of their product against the Ferinject Injection of M/s. Vifor Pharma UK Limited.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Nanjing Hencer Pharmaceutical Co., Ltd No. 18 Jichang Road, Lishui Economic & Technological Development Zone, Nanjing City, Jiangsu Province, China		
API Lot No.	R211101		
Description of Pack (Container closure system)	A dark brown color sterile solution filled in 10ml clear tubular glass vial of USP type 1, plugged with rubber stopper of USP type 1 & sealed with red color aluminum flip off seal, further 1 vial packed in a unit carton with insertion of a leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2000 AMPOULES	2000 AMPOULES	2000 AMPOULES

Manufacturing Date	11/2022	11/2022	11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. JS20180811) valid till 06-05-2023 issued by Jiangsu Food And Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	1.6.5	Valid GMP certificate/DML of drug substance manufacturer shall be submitted issued by relevant regulatory authority of country of origin.	Firm submitted the valid GMP certificate issued by relevant regulatory authority of country of origin.
2.	2.3.R.1.1	Complete batch manufacturing record of three stability batches shall be submitted.	Firm submitted BMR of all three trial batches.
3.	3.2.S.4.2	Drug substance specifications and analytical procedure shallbe submitted from drug product manufacturer, based upon the standards applied by drug substance manufacturer.	Firm submitted the drug substance specification and analytical procedure in accordance with drug substance manufacturer.
4.	3.2.P.1	Clarification shall be submitted regarding the container closure system, whether ampoule or vial.	Firm clarify that they used ampoule for packaging of injection.
5.	3.2.P.3.3	Provide details regarding the method of sterilization of the drug product.	Submitted the complete details of sterilization process.
6.	3.2.P.8.3	Documents confirming import of drug substance with approval from DRAP I&E Office, shall be submitted	Submitted

Decision: Approved.

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

426.	Name, address of Applicant / Marketing Authorization Holder	M/s SWERA Pharmaceuticals Plot # 27, Street # S-4, National Industrial Zone Rawat

		Islamabad.
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals Plot # 27, Street # S-4, National Industrial Zone Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 14/09/2021 based on inspection dated 30-06-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-09-2021 specifying Capsules (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25742 dated 24-10-2023
	Details of fee submitted	PKR 30,000/- Dated 24-10-2023
	The proposed proprietary name / brand name	**Swepra 20mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole ……. 20mg
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)
	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in Ivory/green hard gelatin capsule shells
	Reference to Finished product specifications	USP
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 20mg Capsules (European Medicines Agency Approved)
	For generic drugs (me-too status)	Prazmic 20mg Capsules by M/s Honig Pharma Rawalpindi, Reg. No. 091734
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical proceduresand its validation, batch analysis and justification ofspecification, reference standard, container closure system

		and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Risek 20mg Capsules manufactured by Abbot Laboratories Pakistan. Firm has submitted CDP results of their product against the innovator's product Risek 20mg Capsules in 2 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad-Pakistan.		
API Lot No.	OMP1160		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-C018	RD-C019	RD-C020
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	18-02-2023	21-02-2023	22-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-26/2019-Addl.Dir.(QA & LT1)-56) dated 22-08-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm is new DML. In nearby future we will put efforts to be 21 CFR complaint.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.P.2.2.1	Justify for not performing uniformity of dosage unit test while establishing the pharmaceutical equivalence against the reference product.	Firm replied that the content uniformity of dosage unit has not been performed due to negligence and we undertake that we will perform the test while establishing commercial batches.
2.	3.2.P.8	Justify for not performing uniformity of dosage unit test while performing the stability study of drug product.	Firm replied that content uniformity of the dosage unit will be definitely performed during the stability studies of commercial batches.

Decision: Approved. Registration letter will be issued upon submission of performance data of "Uniformity of dosage unit test" by way of Content Unirformity, at next time point of long term stability studies.

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

427.	Name, address of Applicant / Marketing Authorization Holder	M/s. SWERA Pharmaceuticals Plot # 27, Street # S-4, National Industrial Zone Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals Plot # 27, Street # S-4, National Industrial Zone Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 14/09/2021 based on inspection dated 30-06-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-09-2021 specifying Capsules (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25743 dated 24-10-2023
	Details of fee submitted	PKR 30,000/- Dated 24-10-2023
	The proposed proprietary name / brand name	**Swepra 40mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole ……. 40mg
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)

	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in Purple/purple hard gelatin capsule shells
	Reference to Finished product specifications	USP
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg Capsules (European Medicines Agency Approved)
	For generic drugs (me-too status)	Prazmic 40mg Capsules by M/s Honig Pharma Rawalpindi, Reg. No. 091735
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Risek 40mg Capsules manufactured by Abbot Laboratories Pakistan. Firm has submitted CDP results of their product against the innovator's product Risek 40mg Capsules in 2 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad-Pakistan.
API Lot No.	OMP1160

Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-C021	RD-C022	RD-C023
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	02-2023	03-2023	03-2023
Date of Initiation	26-02-2023	02-03-2023	03-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-26/2019-Addl.Dir.(QA & LT1)-56) dated 22-08-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm is new DML. In nearby future we will put efforts to be 21 CFR complaint.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Response of Firm
1.	3.2.P.2.2.1	Justify for not performing uniformity of dosage unit test while establishing the pharmaceutical equivalence against the reference product.	Firm replied that the content uniformity of dosage unit has not been performed due to negligence and we undertake that we will perform the test while establishing commercial batches.
2.	3.2.P.8	Justify for not performing uniformity of dosage unit test while performing the stability study of drug product.	Firm replied that content uniformity of the dosage unit will be definitely performed during the stability studies of commercial batches.

Decision: Approved. Registration letter will be issued upon submission of performance data of "Uniformity of dosage unit test" by way of Content Uniformity at next time point of long term stability studies.

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

428.	Name, address of Applicant / Marketing Authorization Holder	M/s SWERA Pharmaceuticals Plot 27, Street S-4, National Industrial Zone Rawat Islamabad
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals Plot 27, Street S-4, Industrial Area Rawat Islamabad

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 14/09/2021 based on inspection dated 30-06-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-09-2021 specifying Tablets (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20073 dated 15/08/2023
	Details of fee submitted	PKR 30,000/-: dated 15/08/2023
	The proposed proprietary name / brand name	**Itopsar 50mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Itopride hydrochloride …….50mg
	Pharmacotherapeutic Group of (API)	Gastro prokinetic
	Pharmaceutical form of applied drug	White to off white rounded film coated tablets packed in PVC blister
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ganaton 50mg Tablets PMDA Japan
	For generic drugs (me-too status)	Ganaton 50mg Tablets by M/s Abbot Laboratories Pakistan Ltd Karachi. (Reg.No. 028429)
	Name and address of API manufacturer.	Vasudha Pharma Chem Limited, Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), Visakhapatnam- 531019, Andhra Pradesh, India, Phone: +91-8924-236 228
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Ganaton Tablet 50mg manufactured by Abbot Laboratories Pakistan Ltd. Firm has submitted CDP results of their product against the innovator's product Ganaton Tablet 50mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vasudha Pharma Chem Limited, Unit-III, Plot No. 23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), Visakhapatnam- 531019, Andhra Pradesh, India, Phone: +91-8924-236 228		
API Lot No.	CITP/2110017		
Description of Pack (Container closure system)	PVC blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-T016	RD-T017	RD-T018
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	22-12-2022	23-12-2022	24-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 31/VP/AP/2012/B/R issued by DCA Chuutugunta Guntur valid till 13/12/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 12-04-2022 of Itopride HCl. The invoice is cleared by AD (I&E) DRAP, Islamabad.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm is new DML. In nearby future we will put efforts to be 21 CFR complaint.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	3.2.P.5.2	Justify for keeping the wider acceptance criteria for dissolution of drug product, since more than 90% drug dissolved within 15 min as evident from submitted CDP report.	Firm replied that "The wider acceptance criteria for dissolution was kept as no data for dissolution is available in the reviews of the innovator product. Furthermore, wider acceptance criteria was also kept for the reason to be on the safe side as general chapters of pharmacopeia for dissolution of immediate release formulations recommend the criteria of 30 minutes with 80%(Q).

Decision: Approved.

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

429.	Name, address of Applicant / Marketing Authorization Holder	M/s SWERA Pharmaceuticals Plot # 27, Street # S-4, National Industrial Zone Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals Plot # 27, Street # S-4, National Industrial Zone Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 14/09/2021 based on inspection dated 30-06-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 16-09-2021 specifying Capsules (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 15969 dated 23-06-2023
	Details of fee submitted	PKR 30,000/- Dated 23-06-2023
	The proposed proprietary name / brand name	**Lansoera 30mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric Coated Pellets of Lansoprazole eq. to Lansoprazole ……. 30mg (Product Specs: USP)
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)

	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in Red/white hard gelatin capsule shells
	Reference to Finished product specifications	USP
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Prevacid 30mg Capsules (USFDA Approved)
	For generic drugs (me-too status)	Selanz 30mg Capsules by M/s Searle Pakistan, Reg. No. 110185
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, containerclosure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Prevacid 30mg Capsules manufactured by Takeda Pharma USA. Firm has submitted CDP results of their product against the innovator's product Prevacid 30mg Capsules in 2 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad-Pakistan.
API Lot No.	LPS0426

Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-C015	RD-C016	RD-C017
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	28-09-2022	28-09-2022	29-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-26/2019-Addl.Dir.(QA & LT1)-56) dated 22-08-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm is new DML. In nearby future we will put efforts to be 21 CFR complaint.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.7	Submit readable copy of stability data of drug substance.	Firm submitted the stability data of drug substance.
2.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.	Firm submitted the picture of the innovator product against which the pharmaceutical equivalence/CDP has been performed is being submitted.
3.	3.2.P.2.2.1	Justify for not performing the content uniformity test while establishing the pharmaceutical equivalence against the innovator product.	Firm replied that content uniformity test is not applicable on the product having dose larger than 25mg as evident from USP pharmacopeial reference attached for your kind consideration. However, the dose uniformity test has been performed on the basis of weight variation. However the USP monograph of "Lansoprazole Delayed release capsule" includes the test of uniformity of dosage units

4.	3.2.P.5	Justify for not performing the dissolution test in accordance with USP monograph, since the wavelength and the formula used for calculation is different from that specified in USP monograph of Lansoprazole delayed release capsule.	Firm replied that the revised dissolution test report has been submitted, which is performed in accordance with USP monograph.	
5.	3.2.P.8	Justify for keeping the injection volume 20µl while performing the assay of drug product as evident from the submitted chromatogram, since the USP monograph recommends 10µl injection volume for assay of Lansoprazole delayed release capsule.	Firm replied that due to availability of 20 µl injector in our HPLC system they have use 20 µl injection volume.	
6.	2.3.R.1.1	Provide detailed calculation of dispensed weight of API (enteric coated pellets) per capsule considering the calculated potency of drug substance.	Submitted	

Decision: Deferred for the submission of performance of following tests as per USP monograph of "Lansoprazole Delayed-Release Capsules" at the next time point of long term stability studies:

- **Uniformity of Dosage Units.**
- **Dissolution**

430.	Name, address of Applicant / Marketing Authorization Holder	M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur
	Name, address of Manufacturing site.	M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	afresh license granted on 10/11/2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Capsules (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26128 dated 30-10-2023
	Details of fee submitted	PKR 30,000/- Dated 26-10-2023
	The proposed proprietary name / brand name	**PTL Tablet 40mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric coated tablet contains: Pantoprazole as sodium sequihydrate…40mg
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)
	Pharmaceutical form of applied drug	White to off white circular round enteric coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory	USFDA Approved

	authorities	
	For generic drugs (me-too status)	Neege 40mg Tablet by M/s Searle Pakistan, Reg. No. 110185
	Name and address of API manufacturer.	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andra pardesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, containerclosure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Neege 40mg Tablet of M/s. Searle Pharma. Firm has submitted CDP results of their product against the reference product Neege 40mg Tablet of M/s. Searle Pharma. in 2 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andrapardesh, India.
API Lot No.	NA
Description of Pack (Container closure system)	Alu-alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MA-PT-001	MA-PT-002	MA-PT-003
Batch Size	550 Tablets	550 Tablets	550 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	25-01-2023	25-01-2023	25-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate no. WC-0494 issuing date 26-02-2021 and valid until three years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1- 3.2.S.4.2	Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
2.	3.2.S.4.3	Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
3.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
4.	3.2.S.7	COA of USP complied drug substance is submitted in section 3.2.S.4.4 while the stability data of EP complied drug substance has given in relevant section; clarification is required in this regard. Submit stability data of drug substance till the claimed re-test date, since you have submitted the long term data of only 24 months.
5.	3.2.P.1	Justify the formulation which is different in terms of qualitative composition from that of innovator product.
6.	3.2.P.2.2.1	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.
7.	3.2.P.8	• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. • Documents for the procurement of API with approval from DRAP (in case of import).

		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
8.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.	

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

431.	Name, address of Applicant / Marketing Authorization Holder	M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.
	Name, address of Manufacturing site.	M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 18/02/2021
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-43/2006-Lic (Vol-I) dated 10/06/2021. Tablet (general), Capsule (general),Topical/cream/ointment/gel (general), Oral dry powder suspension (Cephalosporin section) and Capsule (Cephalosprin) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No.22772 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 15-05-2023
	The proposed proprietary name / brand name	Diclosaf SR 100MG Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Diclofenac sodium..... 100mg.
	Pharmacotherapeutic Group of (API)	NSAIDS
	Pharmaceutical form of applied drug	White to off white sustained release pellets filled in hard gelatin capsules
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not confirmed
	For generic drugs (me-too status)	Phologen SR 100mg Capsule (Reg.no.009129) of M/s. Brookes Pharma, Karachi
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP studies of their product against the Phologen SR 100mg Capsule (Reg.no.009129) of M/s. Brookes Pharma, Karachi
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.		
API Lot No.	DE959ER		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR031	TR032	TR033
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-26/2019-Addl.Dir.(QA & LT1)-56) dated 22-08-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--

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

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.5.2	Submit the correct label claim of applied product in accordance with the label claim of reference product along with the requisite fee.
2.	3.2.S.4.2	• Justify for including the Acid resistance stage in the dissolution test of sustained release pellets by the drug substance manufacturer. • Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.S.4.4	Justify for specifying the results of acid resistance stage in the dissolution test of sustained release pellets. COA of drug substance contain note "pellets will remain intact, during buffer stage due to sugar free nature", clarification is required regarding this statement for the sustained release pellets.
5.	3.2.P.1	Please explain the role of empty gelatin capsule in the potency of finished drug product, since you have mentioned in the master formulation that the quantity of diclofenac sodium SR pellets used 80.40% and 19.60% of empty gelatin shell has taken to make 100%.
6.	3.2.P.5.2	• Submit detailed procedure how you have performed uniformity of dosage unit test while quality analysis of drug product. • Justify for including the Acid resistance stage in the dissolution test of sustained release pellets by the drug product manufacturer.
7.	3.2.P.6	Justify of using USP complied working standard of diclofenac sodium for the analysis of BP complied drug product and how the drug substance manufacturer provide USP complied working standard when they are supplied in house specified diclofenac sodium pellets.
8.	3.2.P.8	According to the analytical method verification report absorbance value of sample and standard solution was around 0.3 while the obtained absorbance value during assay performance of stability batches were around 0.6, clarify the variation observed in the absorbance value obtained.
9.	2.3.R.1.1	Provide detailed calculation of weight of pellet filled per capsule considering the potency of diclofenac pellets.

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

432.	Name, address of Applicant / Marketing Authorization Holder	M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.
	Name, address of Manufacturing site.	M/s. Safina Pharmaceuticals (Pvt.) Ltd. 17-Km, Lahore-Sheikhupura Road, District Shiekhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license granted on 18/02/2021
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-43/2006-Lic (Vol-I) dated 10/06/2021. Tablet (general), Capsule (general),Topical/cream/ointment/gel (general), Oral dry powder suspension (Cephalosporin section) and Capsule (Cephalosprin) sections are approved.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No.22771 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 15-05-2023
	The proposed proprietary name / brand name	Diclosaf 50mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Diclofenac sodium .....50mg.
	Pharmacotherapeutic Group of (API)	NSAIDS
	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in hard gelatin capsules
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Voltaren 50mg Capsule USFDA Approved
	For generic drugs (me-too status)	Phologen 50mg Capsule (Reg.no.009128) of M/s. Brookes Pharma, Karachi
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities,physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure

		system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence & CDP studies of their product against the Mobikare 50 Capsules of M/s. Barret & Hodgson Pakistan (Batch no. D3560)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan. (Diclofenac sodium enteric coated pellets (33%)		
API Lot No.	DE617		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR025	TR026	TR027
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	08-2022	08-2022	08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-26/2019-Addl.Dir.(QA & LT1)-56) dated 22-08-2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.5.2	Submit the correct label claim of applied product in accordance with the label claim of reference product along with the requisite fee.
2.	3.2.S.4.2	Submit specification and detailed analytical procedure of drug substance by drug product manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.P.1	Please explain the role of empty gelatin capsule in the potency of finished drug product, since you have mentioned in the master formulation that the quantity of

		diclofenac sodium EC pellets used 75.88% and 24.12% of empty gelatin shell has taken to make 100%.	
5.	3.2.P.5.2	Submit detailed procedure how you have performed uniformity of dosage unit test while quality analysis of drug product.	
6.	3.2.P.6	Justify of using USP complied working standard of diclofenac sodium for the analysis of BP complied drug product and how the drug substance manufacturer provide USP complied working standard when they are supplied in house specified diclofenac sodium pellets.	
7.	2.3.R.1.1	Provide detailed calculation of weight of pellet filled per capsule considering the potency of diclofenac pellets.	

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

433.	Name, address of Applicant / Marketing Authorization Holder	Himark Laboratories (Pvt.) Ltd. Plot no. 37-A, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	Himark Laboratories (Pvt.) Ltd. Plot no. 37-A, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate based upon the evaluation conducted on 28-03-2023.
	Evidence of approval of manufacturing facility	License granted vide letter No. F. 1-67/2005- Lic dated 26TH September,2019. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and Oral Liquid Syrup (general) sections and Cream/Ointment (General) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 25278 dated 17-10-2023
	Details of fee submitted	Rs.30,000/- dated 02-10-2023
	The proposed proprietary name / brand name	Declor Syrup 2.5mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Desloratadine… 0.5mg
	Pharmacotherapeutic Group of (API)	Antihistamine H1 antagonist
	Pharmaceutical form of applied drug	Oral Syrup
	Reference to Finished product specifications	In-house
	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)	Desora 0.5mg/ml Syrup of M/s. Continental Pharma (Reg.no.055192)
	Name and address of API manufacturer.	M/s. Morepen Laboratories Limited Village Masulkhana, Perwanoo Distt. Solan Perwanoo Himachal Pardesh, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 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, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence their product against the clarinex Syrup of M/s. Merck & Co. Inc.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Morepen Laboratories Limited Village Masulkhana, Perwanoo Distt. Solan Perwanoo Himachal Pardesh, India.		
API Lot No.	DH-0106		
Description of Pack (Container closure system)	Amber color pet bottle with Aluminium Cap is packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12,18,24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	01-2023	01-2023	01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HFW-H (Drugs) 56/98 issued dated 10/01/2022 by

		Health & Family Welfare Department Himachal Pardesh and valid for two years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted commercial invoice without DRAP attestation.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Drug substance analytical procedure shall be submitted from both drug substance manufacturer and drug product manufacturer.
2.	3.2. P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
3.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
4.	3.2.P.4	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.
5.	3.2.P.5.2	• Clarification required regarding the instrument used for assay of drug product either the assay has performed on HPLC or UV spectrophotometer. Since the assay method given in section 3.2.P.5.2 is on UV while validation report and stability data revealed that the assay has been performed on HPLC. • Provide detailed procedure of uniformity of dosage unit test and deliverable volume test.
6.	3.2.P.5.4	Provide results of impurity testing relevant to the presence of ethylene glycol and diethylene glycol contamination in the drug in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.
7.	3.2.P.8	• Justify the batch size against the number of units to complete stability studies. • Documents confirming import of drug substance with approval from DRAP I&E Office, shall be submitted. • Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
8.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

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

Cases of Priority Molecules received on form 5-F:

434.	**Name, address of Applicant / Importer**	**M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd. Plot no. 36-A, PSIC, SIE, Taxila, Rawalpindi**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D Address: Plot no. 36-A, PSIC, SIE, Taxila, Rawalpindi Address of Godown: Plot no. 36-A, PSIC, SIE, Taxila, Rawalpindi Validity: 04-08-2024 Status: Valid
	Name and address of marketing authorization holder (abroad)	M/s. Jiangsu Hengrui Medicine Co. Ltd. 7 Kunlunshan Road, Economic and Technological Development Zone Lianyungang Jiangsu 222047 China

	Name, address of manufacturer(s)	M/s. Jiangsu Hengrui Medicine Co. Ltd. Dongjin Road, Port Industry Area, Economic and Technological Development Zone, Lianyungang, Jiangsu, China
	Name of exporting country	United States of America(as per the submitted copy of CoPP)
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted a commitment letter "that they shall submit the original embassy legalized valid Certificate of Pharmaceutical Product (CoPP) of applied product Iodopaque Injection 320mgI/ml-100ml vial within 3 months. GMP Certificate: Firm has submitted GMP Certificate No. Su20160311 issued by Jiangsu Drug Administration. The GMP conforms the regulations with the requirements of PIC/s and the Directives of the European Commission.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Distribution Certificate from M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd., No. 38, Huanghe Road, Economic& Technological Development Zone, Lianyungang. The letter specifies that the manufacturer authorize M/s. Lab Diagnostics System (SMC) Pvt. Ltd. to sell and participate on behalf of Jiangsu Hengrui Pharmaceuticals Co. Ltd. in government, semi government and other local tender and sign sale contracts pertaining to the aforesaid tenders and also allowed to distribute our products (brand name: IODOPAQUE Injection 320mg I/ml (100 ml & 200ml) 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. 27225 dated 17th November,2023
	Details of fee submitted	PKR 150,000/- vide slip no. 93315011 dated: 25-10-2023
	The proposed proprietary name / brand name	Iodopaque Injection 320mgI/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	320mg Iodine/ml (100ml vial)
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Iodinated Contrasting Media
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA (Iodixanol 350mgI/ml,100ml)
	For generic drugs (me-too status)	Visipaque 320mgI/ml (50ml as per available data)(Reg.no.043052) M/s. Bayer

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure,general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd. (Jinqiao Road Site) 22 Jinqiao Road, Dapu Industrial Park, Economic and Technological Development Zone, Lianyungang, Jiangsu 222002, 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, 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 accelerated and real time stability data are conducted at (40±2ºC/75±5%RH) and (25±2ºC/60±5%RH) respectively. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate products, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report against the reference listed drug Visipaque 320 NDA 020351 of M/s. GE Healthcare.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Iodixanol Injection 320mgI/ml is filled into 100ml colourless and translucent polypropylene bottle, sealed with a d=grey bromobutyl rubber stopper and secured with a colorless polypropylene cap (PP cap) with tamper-evident ring.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of batches of volume sizes 50ml,100ml & 150ml. The accelerated stability study data is conducted at 40ºC ±2ºC / 20% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC /35 % ± 5% RH.

Evaluation by PEC:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.3	Submit valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin. Further, clarification is required either the drug product is import from China or United States of America, since you have submitted the copy of CoPP/ Free sale certificate in which the exporting country is United State of America, while the Manufacturer, manufacturing authorization holder and letter of authorization is M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd. China .

Decision: Deferred for submission of valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin. Further, clarification is required either the drug product is imported from China or United States of America, since you have submitted the copy of CoPP/ Free sale certificate in which the exporting country is United State of America, while the Manufacturer, manufacturing authorization holder and letter of authorization is from M/s. Jiangsu Hengrui Pharmaceuticals Co. Ltd. China .

Contract manufacturing applications as per decision of 173rd meeting of Authority:

Authority in its 173rd meeting has decided as under:

"The Authority, in order to further enhance the working efficiency and quick disposal of pending registration applications, approved to create a separate queue for registration applications for contract manufacturing submitted on Form-5F in the order of date of submission. This Queue will be updated after each meeting of Registration Board."

435.	Name, address of Applicant / Marketing Authorization Holder	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Name, address of Manufacturing site.	M/s. Bio-Lab (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of Panel inspection of M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad dated 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 recommends renewal of DML and indicates Dry Powder Injection (General).
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section letter of M/s. Bio-Labs (Pvt.) Ltd. Dated 27th September,2021, in which firm has grant additional section Dry Vial Injection (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.7095 : dated 10-03-2023
	Details of fee submitted	PKR 75,000/-: 07-11-2022
	The proposed proprietary name / brand name	Prazovant 40mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Pantoprazole sodium equivalent to Pantoprazole…40mg
	Pharmaceutical form of applied drug	Lyophilized Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	NEEGE 40mg Injection of M/s Sami Pharma (Reg # 057832)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Zopent 40mg Injection of Nabi Qasim Pharmaceuticals
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	2109901		
Description of Pack (Container closure system)	Tubular Type-I glass vial filled with almost white colored sterile powder		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PNT 21-001	PNT 21-002	PNT 21-003
Batch Size	1633 vials	1633 vials	1633 vials

Manufacturing Date		11-21	11-21	11-21
Date of Initiation		04-11-2021	04-11-2021	04-11-2021
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	submitted		
2.	Approval of API/ DML/GMP certificate of API manufacturerissued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Vision pharma pvt Ltd, Lahore issued by DRAP Lahore. It is valid till 10-02-2022.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of pantoprazole sodium sterile powder (570gM, Batch # 2109901) from M/s vision pharma vide invoice # 600091 dated 04-10-2021.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings
1.	• Justification of addition of mannitol as an excipient in the preparation of lyophilized dry powder injectable. • Justify the quantity of EDTA used in the formulation with reference to the quantity mentioned in the document of innovator product.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer in section 3.2.S.4.3.
3.	The assay limit specified by drug substance manufacturer is 36% to 40% w/w while you have defined the assay limit as 34% to 40%. Justify how drug product manufacturer can change the assay limits.
4.	Analytical procedure used for the analysis of drug substance by drug product manufacturer is different from the analytical method specified by drug substance manufacturer, justification is required in this regard.
5.	Justify for performing the stability study on drug substance packaged in glass vial, while the container closure described in section 3.2.S.6 is aluminium tin.
6.	Submit stability data of drug substance packaged in aluminum tin as per the described container closure in section 3.2.S.6 performed both at accelerated and long term condition till the claimed re-test period
7.	• Justify the declared potency of pantoprazole working standard 89% with reference to submitted COA of reference standard. • Expiry date of primary reference standard was 20-07-2021 and the retest date mentioned on the submitted COA of working standard is 19-01-2021, while the stability initiation date of trial batches was 04-11-2021, clarification is required how the submitted expired COA of reference standard is used for the analysis of stability trial batches.
8.	Submit updated stability data of drug product, since you have only submitted the real time stability data of 6 months.
9.	Submit complete calculation of dispensed quantity of active per vial specifically with reference to the adjustment of salt factor.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
436.	Name, address of Applicant / Marketing Authorization Holder	M/s Fedro Pharmaceuticals Laboratories Private Limited. 149-Industrial Estate, Hayatabad, Peshawar
	Name, address of Manufacturing site.	M/s. Bio-Lab (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of Panel inspection of M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad dated 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 recommends renewal of DML and indicates Dry Powder Injection (General).
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section letter of M/s. Bio-Labs (Pvt.) Ltd. Dated 27th September,2021, in which firm has grant additional section Dry Vial Injection (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7083 : dated 10-03-2023
	Details of fee submitted	PKR 75,000/-: 07-11-2022
	The proposed proprietary name / brand name	**Pantoprazole 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Pantoprazole sodium equivalent to Pantoprazole…40mg
	Pharmaceutical form of applied drug	Lyophilized Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	NEEGE 40mg Injection of M/s Sami Pharma (Reg # 057832)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Zopent 40mg Injection of Nabi Qasim Pharmaceuticals
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	2109901		
Description of Pack (Container closure system)	Tubular Type-I glass vial filled with almost white colored sterile powder		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PNT 21-001	PNT 21-002	PNT 21-003
Batch Size	1633 vials	1633 vials	1633 vials
Manufacturing Date	11-21	11-21	11-21
Date of Initiation	04-11-2021	04-11-2021	04-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	submitted
2.	Approval of API/ DML/GMP certificate of API manufacturerissued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Vision pharma pvt Ltd, Lahore issued by DRAP Lahore. It is valid till 10-02-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of pantoprazole sodium sterile powder (570gM, Batch # 2109901) from M/s vision pharma vide invoice # 600091 dated 04-10-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings
1.	• Justification of addition of mannitol as an excipient in the preparation of lyophilized dry powder injectable. • Justify the quantity of EDTA used in the formulation with reference to the quantity mentioned in the document of innovator product.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer in section 3.2.S.4.3.
3.	The assay limit specified by drug substance manufacturer is 36% to 40% w/w while you have defined the assay limit as 34% to 40%. Justify how drug product manufacturer can change the assay limits.
4.	Analytical procedure used for the analysis of drug substance by drug product manufacturer is different from the analytical method specified by drug substance manufacturer, justification is required in this regard.
5.	Justify for performing the stability study on drug substance packaged in glass vial, while the container closure described in section 3.2.S.6 is aluminium tin.
6.	Submit stability data of drug substance packaged in aluminum tin as per the described container closure in section 3.2.S.6 performed both at accelerated and long term condition till the claimed re-test period
7.	• Justify the declared potency of pantoprazole working standard 89% with reference to submitted COA of reference standard. • Expiry date of primary reference standard was 20-07-2021 and the retest date mentioned on the submitted COA of working standard is 19-01-2021, while the stability initiation date of trial batches was 04-11-2021, clarification is required how the submitted expired COA of reference standard is used for the analysis of stability trial batches.
8.	Submit updated stability data of drug product, since you have only submitted the real time stability data of 6 months.
9.	Submit complete calculation of dispensed quantity of active per vial specifically with reference to the adjustment of salt factor.

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

Previously Deferred Cases of Form 5-F:

a. Cases of Finished Import

437.	**Name, address of Applicant / Importer**	**M/s Grace Pharmaceuticals**
	Details of Drug Sale License of importer	License No. 152 Address: Office no. 503, 5th floor Plot no 42C/2 Lane-08, Bukhari Commercial Phase-6, D.H.A Karachi, Pakistan.

		Address of Go down: NA Validity: 21-10-2023 Status: License to sell drugs as distributor Renewal: Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name, address of manufacturer(s)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted notarized (notarized by Beijing Fangyuan Notary Public Office) copy of CoPP certificate (No: 20210127) dated 23-03-2021 issued by Beijing Municipal Medical Product Administration CHINA for Iodixanol injection 50ml. 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. Furthermore the CoPP was valid till 31-10-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beijing Beilu Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints M/s Grace Pharmaceuticals. To register their products in Pakistan. The authorization letter is valid till 30-04-2026.
	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. 153 : 03-01-2022
	Details of fee submitted	PKR 75,000/-: vide slip no. 5548215985
	The proposed proprietary name / brand name	Intrapaque 50 mL : 16g I Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Iodixanol …….50ml (50ml:16g I)
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Medical Imaging Drug
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 VIAL
	Proposed unit price	N/A
	The status in reference regulatory authorities	Visipaque® 320mg Iodine/ml GE Healthcare AS USFDA APPROVED

	For generic drugs (me-too status)	Visipaque 320mgI/ml (50ml as per available data)(Reg.no.043052) M/s. Bayer
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	GE Healthcare As Lindesnesveien208, N0-4551 Lindesnes, Norway
	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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of IODIXANOL Injection instead of iodixanol API. The real time stability data is conducted at 30 ℃±2, RH 65%±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, containerclosure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the comparative study on quality of iodixanol injection (50ml:16mg(I) between reference preparation and self-made preparation.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Medium borosilicate glass infusion bottle, strength: 50ml Bottle Pack: Halogenated butyl rubber stopper for injection (chlorinated), strength: 32mm Aluminum-plastic composite cover for infusion bottle, strength: 32mm
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. Accelerated Stability batches: R200101, R200102, R200103 Real Time Stability Batches: R200102 (18 months) R200103 (36 months)
VISIPAQUE is indicated in for: 1.1 Intra-arterial Procedures Adult and pediatric patients 12 years of age and older • (270 and 320 mg Iodine/mL) intra-arterial digital subtraction angiography (IA-DSA). • (320 mg Iodine/mL) angiocardiography (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography. Pediatric patients less than 12 years of age		

• (320 mg Iodine/mL) angiocardiography, cerebral arteriography, and visceral arteriography. 1.2 Intravenous Procedures Adult and pediatric patients 12 years of age and older
• (270 and 320 mg Iodine/mL) CT imaging of the head and body.
• (270 and 320 mg Iodine/mL) excretory urography.
• (270 mg Iodine/mL) peripheral venography.
• (320 mg Iodine/mL) coronary computed tomography angiography (CCTA) to assist in the diagnostic evaluation of patients with suspected coronary artery disease. Pediatric patients less than 12 years of age
• (270 mg Iodine/mL) CT imaging of the head and body.
• (270 mg Iodine/mL) excretory urography.
Evaluation by PEC:
Firm has to be submit requisite fee for imported product, since the Me-Too of 50ml is available in the record.

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted CoPP is invalid.	
2.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".
3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".*
5.	3.2.S.5	Submit COA of reference standards in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable. COA of primary / secondary reference standard including source and lot number shall be provided".*
6.	3.2.S.6	Submit details of container closure system of drug substance in section 3.2.S.6 as per the guidance document approved by Registration Board which specifies that "*Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component. Other information on the container closure system(s) (e.g. suitability studies) may be submitted".*
7.	3.2.S.7	Submit data in section 3.2.S.7 as per the guidance document approved by Registration Board which specifies that "The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted". Since you have submitted the compatibility results of Iodixanol with excipient.

8.	3.2.P.2.2.1	Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.
9.	3.2.P.5.3	Submit data of verification of assay procedure of drug product in section 3.2.P.5.3 as per the guidance document approved by Registration Board which specifies that "*All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy".*

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted CoPP is invalid.		Firm submitted the copy of CoPP certificate no.20230045 issue dated 13-02-2023 by Biejing Municipal Medical Product Administration, which is valid till 12-02-2025.
2.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".	Firm submitted the specification and analytical procedure of drug substance by drug product manufacturer i.e. M/s. Beijing Beilu Pharmaceutical Co., Ltd, while drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug substance manufacturer i.e. M/s. GE Healthcare As. has not been submitted.
3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 asper the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm replied that "Bielu analyzes API according to USP compendial method. So Bielu Pharmaceuticals did not conduct methodological validation.
4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product*	Firm submitted Batch analysis report of drug substance only by drug product manufacturer.

		development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".		
5.	3.2.S.5	Submit COA of reference standards in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable. COA of primary / secondary reference standard including source and lot number shall be provided".*	Firm has not submitted the COA of reference standard of iodixanol.	
6.	3.2.S.6	Submit details of container closure system of drug substance in section 3.2.S.6 as per the guidance document approved by Registration Board which specifies that "*Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component. Other information on the container closure system(s) (e.g. suitability studies) may be submitted".*	Firm submitted the requisite details.	
7.	3.2.S.7	Submit data in section 3.2.S.7 as per the guidance document approved by Registration Board which specifies that "The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted". Since you have submitted the compatibility results of Iodixanol with excipient.	Firm submitted the stability data of drug substance submitted by drug product manufacturer (M/s. Biejing Bielu Pharmaceuticals Co. Ltd., China instead of M/s. GE Health care, Norway) till 18 months while the claimed shelf life mentioned on the document is 36 months.	
8.	3.2.P.2.2.1	Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in	Firm submitted the details of reference product i.e. Reference preparation Manufacturing: GE Healthcare As Expiry date: 36 months.	

		pharmaceutical equivalence studies.		
9.	3.2.P.5.3	Submit data of verification of assay procedure of drug product in section 3.2.P.5.3 as per the guidance document approved by Registration Board which specifies that "*All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy".*	Firm submitted the analytical method validation report of assay procedure of drug product.	

Decision: Deferred for submission of following:

- **Submit specification and analytical procedure of drug substance used by drug substance manufacturer.**
- **Provide analytical method verification report of drug substance performed by drug product manufacturer.**
- **Submit Certificate of analysis of API from drug substance manufacturer.**
- **Submit complete stability data of drug substance conducted at both accelerated and long term condition till the claimed re-test date, performed by the drug substance manufacturer.**

438.	Name, address of Applicant / Importer	M/s Grace Pharmaceuticals
	Details of Drug Sale License of importer	License No. 152 Address: Office no. 503, 5th floor Plot no 42C/2 Lane-08, Bukhari Commercial Phase-6, D.H.A Karachi, Pakistan. Address of Go down: NA Validity: 21-10-2023 Status: License to sell drugs as distributor Renewal: Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name, address of manufacturer(s)	Beijing Beilu Pharmaceutical Co., Ltd. No. 3 Shuiyuan West Road, Miyun District, Beijing, 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: 20210349) dated 18 Aug, 2021 issued by Beijing Municipal Medical Product Administration CHINA for Iodixanol injection 100ml. The CoPP confirms free sale status of the product in exporting country as well as GMP statusof the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned. Furthermore the CoPP was valid till 12-12-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beijing Beilu Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints M/s Grace Pharmaceuticals. To register their products in Pakistan. The authorization letter is valid till 30-04-2026.
	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.5508 : 28-02-2022
	Details of fee submitted	PKR 75,000/-: vide slip no. 5548215985 dated 10-02-2022
	The proposed proprietary name / brand name	Intrapaque 100mL : 32g I Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Iodixanol…32g(I)
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Medical Imaging Drug
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 VIAL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Visipaque® 320mg Iodine/ml GE Healthcare AS USFDA APPROVED
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	GE Healthcare As Lindesnesveien208, N0-4551 Lindesnes, Norway
	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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of IODIXANOL Injection instead of iodixanol API. The real time stability data is conducted at 30 ℃±2, RH 65%±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, containerclosure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the comparative study on quality of iodixanol injection (50ml:16mg(I) between reference preparation and self-made preparation.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Medium borosilicate glass infusion bottle, strength: 100ml Bottle Pack: Halogenated butyl rubber stopper for injection (chlorinated), strength: 32mm Aluminum-plastic composite cover for infusion bottle, strength: 32mm
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of 50ml. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH.

VISIPAQUE
is indicated in for: 1.1 Intra-arterial Procedures Adult and pediatric patients 12 years of age and older
• (270 and 320 mg Iodine/mL) intra-arterial digital subtraction angiography (IA-DSA).
• (320 mg Iodine/mL) angiocardiography (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography. Pediatric patients less than 12 years of age
• (320 mg Iodine/mL) angiocardiography, cerebral arteriography, and visceral arteriography. 1.2 Intravenous Procedures Adult and pediatric patients 12 years of age and older
• (270 and 320 mg Iodine/mL) CT imaging of the head and body.
• (270 and 320 mg Iodine/mL) excretory urography.
• (270 mg Iodine/mL) peripheral venography.
• (320 mg Iodine/mL) coronary computed tomography angiography (CCTA) to assist in the diagnostic evaluation of patients with suspected coronary artery disease. Pediatric patients less than 12 years of age
• (270 mg Iodine/mL) CT imaging of the head and body.
• (270 mg Iodine/mL) excretory urography.
Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of theManufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted CoPP is invalid.		Firm submitted the requisite documents.
2.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".	Firm submitted the specification and analytical procedure of drug substance by drug product manufacturer i.e. M/s. Beijing Beilu Pharmaceutical Co., Ltd, while drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug substance manufacturer i.e. M/s. GE Healthcare As. has not been submitted.
3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per	Firm replied that "Bielu analyzes API according to USP compendial method. So Bielu

		the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Pharmaceuticals did not conduct methodological validation.	
4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".*	Firm submitted Batch analysis report of drug substance only by drug product manufacturer.	
5.	3.2.S.5	Submit COA of reference standards in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable. COA of primary / secondary reference standard including source and lot number shall be provided".*	Firm has not submitted the COA of reference standard of iodixanol.	
6.	3.2.S.6	Submit details of container closure system of drug substance in section 3.2.S.6 as per the guidance document approved by Registration Board which specifies that "*Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component. Other information on the container closure system(s) (e.g. suitability studies) may be submitted".*	Firm submitted the requisite details.	

7.	3.2.S.7	Submit data in section 3.2.S.7 as per the guidance document approved by Registration Board which specifies that "The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted". Since you have submitted the compatibility results of Iodixanol with excipient.	Firm submitted the stability data of drug substance submitted by drug product manufacturer (M/s. Biejing Bielu Pharmaceuticals Co. Ltd., China instead of M/s. GE Health care, Norway) till 18 months while the claimed shelf life mentioned on the document is 36 months.	
8.	3.2.P.2.2.1	Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.	Firm has not submitted the requisite information.	
9.	3.2.P.5.3	Submit data of verification of assay procedure of drug product in section 3.2.P.5.3 as per the guidance document approved by Registration Board which specifies that "*All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy".*	Firm submitted the analytical method validation report of assay procedure of drug product.	
10.	3.2.P.8	Provide details/ batch numbers of stability batches of applied formulation, since the batch no. mentioned on the stability summary sheets is same as for 50ml.	Firm submitted the stability data of iohexol instead of stability data of iodixanol (100ml).	

Decision: Deferred for submission of following shortcomings:

- **Submit specification and analytical procedure of drug substance used by drug substance manufacturer.**
- **Provide analytical method verification report of drug substance performed by drug product manufacturer.**
- **Submit Certificate of analysis of API from drug substance manufacturer.**
- **Submit complete stability data of drug substance conducted at both accelerated and long term condition till the claimed re-test date performed by the drug substance manufacturer.**
- **Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.**
- **Submit stability data of drug product (100ml volume size) performed at both accelerated and long term condition till the claimed shelf life.**

439.	**Name, address of Applicant / Marketing Authorization Holder**	**Innovegic Pharmaceuticals** **Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad.**
	Detail of Drug Sale License	License No:1605 Address: Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad. Status:License to sell drug as distributor
	Name and address of Marketing authorization holder(abroad)	ADOH B.V Godfried Bomansstraat 31 6543 JA Nijmegen,The Netherland

	Name, address of Manufacturer	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, 571127, China
	Status of the applicant	☐ Manufacturer ☑ Importer ☐ Is involved in none of the above (contract giver)
	Name of exporting Country	China
	Detail of certificate attached (COPP, Free sale certificate, GMP certificate)	Firm has submitted COPP Certificate No:21-00428 valid up to 11-03-2024 issued by Ministry of Health, Welfare and sport, Netherland and according to which product License holder is ADOH B.V Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland. GMP certificate of Hainan poly pharma was granted by Republic of China valid upto29-01-2024.
	Detail of letter of authorization/sole agency agreement	Submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☑Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10232 dated 21-04-2022
	Details of fee submitted	PKR 150,000/-: dated 14-01-2022
	The proposed proprietary name / brand name	Telisin injection 8.5ml:0.85mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 1mg of terlipressin acetate equivalent to 0.85mg of terlipressin
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Posterior Pituitary Lobe hormone(Vasopressin and analogues)
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	5x8.5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glycopressin injection by Ferring Pharmaceuticals,UK.
	For generic drugs (me-too status)	Europress Injection by M/s Rotex Medica Pharmaceuticals ,Islamabad
	Name and address of API manufacturer.	Chinese Peptide Company No.69,12th Street,HEDA Zhejiang,310018 China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description

		of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies of Drug Substance	Stability study conditions: Real time: 2-8°C for 18 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months Batches: (18082701, 18090601, 18120702)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies of Drug Product	Stability study conditions: Real time: 2-8°C for 36 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months Batches: (T190707, T190708, T190709)
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence performed against RMP Glycylpressin of M/s. Ferring Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.3	• Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since you have submitted the copy of CoPP/ Free sale certificate. • Further, submit letter of authorization/sole agent agreement from Product license holder i.e. M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland. Furthermore, clarify the route of shipment of applied product in Pakistan along with legalized requisite document.
2.	3.2.S.4.1	Justify for not adopting the BP specification for the analysis of drug substance when the monograph of drug substance is available in BP.
3.	3.2.S.4.2	Please clarify the analytical method used for analysis of amino acid, since the submitted procedures of amino acid analysis are not in accordance with the reference general chapter of amino acid i.e.2.2.56 as mentioned in BP monograph of terlipressin.
4.	3.2.S.4.4	Please submit the English translated copy of COA of drug substance by drug substance manufacturer.
5.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.
6.	3.2.P.1	Scientific justification is required for using overage of active ingredient in the formulation along with overfilling of quantity per vial.
7.	3.2.P.2.2.1	Provide pharmaceutical equivalence report in which comparative quality analysis of both tested product and reference product should be presented in the tabulated form.
8.	2.3.R.1.1	Please clarify the fill volume range mentioned in BMR i.e. between 9.12g-9.30g with reference to the label claim of applied product which is 0.85mg Terlipressin (base free) contains in 8.5ml solution.

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Sections	Short-comings	Response of the Firm

1.	1.3.3	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since you have submitted the copy of CoPP/ Free sale certificate.	Firm submit the original legalized CoPP (certificate no. 20230131) issue dated 25-10-2023 by Hainan Provincial Medical Products Administration and valid till 24-10-2025.	
2.	1.3.3	Further, submit letter of authorization/sole agent agreement from Product license holder i.e. M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland. Furthermore, clarify the route of shipment of applied product in Pakistan along with legalized requisite document.	Firm not submitted the reply of this query.	
3.	3.2.S.4.1	Justify for not adopting the BP specification for the analysis of drug substance when the monograph of drug substance is available in BP.	Firm replied that the proposed specification of drug substance is equivalent or stricter than BP monograph of Terlipressin.	
4.	3.2.S.4.2	Please clarify the analytical method used for analysis of amino acid, since the submitted procedures of amino acid analysis are not in accordance with the reference general chapter of amino acid i.e.2.2.56 as mentioned in BP monograph of terlipressin.	Firm replied that the specification and analytical procedure of analysis of amino acid is established as per the specification and analytical procedure listed in CEP of terlipressin, which has been approved by EMA. Since the analytical procedure listed in Ph. Eur. 2.2.56 are the general procedure which are not established for the specific product, so the proposed analytical procedure is not exactly same as the method in Ph. Eur. 2.2.56. The proposed method is specific for the Terlipressin manufactured by Chinese Peptide Company and also the proposed analytical procedure has been fully validated for the use.	
5.	3.2.S.4.4	Please submit the English translated copy of COA of drug substance by drug substance manufacturer.	Submitted	
6.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.	Submitted	
7.	3.2.P.1	Scientific justification is required for using overage of active ingredient in the formulation along with overfilling of quantity per vial. Firm replied that there is no overage in the proposed drug product. The filling weight is determined on analysis on RMP and extractable study. Firstly, the analysis on RMP shows that the filling volume of RMP is about 9ml, so we firstly designed a filling volume of 9ml equivalent to 9.03g, to achieve the quantitative equivalence with the RMP. Secondly, according to USP <1151>, each container of an injection is filled with a volume in slight excess of the labelled size, a series of extractable quantity studies were performed. The study result demonstrated that when control the filling weight above 9.03g (i.e.9ml) the actual available extractable amount can satisfy the labelled amount (8.5ml, equal to 8.53g). The concentration of terlipressin in terlipressin solution for injection is 0.1mg/ml, thus the quantity of terlipressin in each vial should be 0.9mg(calculated on anhydrous, acetic acid free-base). Compared to label amount of 0.85mg, there is about 6% overfill.		

		However, the manufacturer should follow the general guidance of USP <1151> on the target volume i.e. 8.5 ml as per the label claim of drug product instead of targeting the filled volume of reference pack of RMP.		
8.	3.2.P.2.2.1	Provide pharmaceutical equivalence report in which comparative quality analysis of both tested product and reference product should be presented in the tabulated form.	Firm submitted the pharmaceutical equivalence report performed against the product GLYCYLPRESSIN (batch no. N00043C).	
9.	2.3.R.1.1	Please clarify the fill volume range mentioned in BMR i.e. between 9.12g-9.30g with reference to the label claim of applied product which is 0.85mg Terlipressin (base free) contains in 8.5ml solution.	Firm replied that in order to achieve the quantitative equivalence with the RMP and ensure the sufficient extractable quantity (i.e. 0.85mg terlipressin) of terlipressin solutionfor injection, the minimum filling weight is determined to be 9.03g I.e. the lower limit of action level is 9.03g.	

Decision: Deferred forollowing:

- **Clarification is required regarding the product license holder, since the earlier submitted documents revealed that the Product license holder is M/s. ADOH B.V. Godfried Bomansstraat 31 6543 JA Nijmegen, The Netherland and the recently submitted CoPP specified that the product license holder is Hainan poly pharma Co. Ltd., China.**
- **Submit letter of authorization/sole agent agreement from Product license holder. Furthermore, clarify the route of shipment of applied product in Pakistan along with legalized requisite document.**
- **Justify the target fill volume for applied product with reference to the label claim and allowable "Excess Volume in injections" as per USP General Chapter <1151>.**

440.	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/6-110/2016/3305 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, and 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/6-110/06/5027).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. 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.32074 dated 23-11-2021
	Details of fee submitted	PKR 100,000/- 01-02-2021 PKR 50,000/- 12.07.2021
	The proposed proprietary name / brand name	**Sunitix 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Sunitinib Malate INN..... 66.825mg eqv to Sunitinib 50mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	28's
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Sutent 50mg capsule
	For generic drugs (me-too status)	Sutent (Pfizer Laboratories)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 proceduresand 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	Nanjing First Pharmaceuticals Co. Ltd. China Room No.2303,Technical Garden B Place Industrial University No.5 Xinmofang Road, Nanjing, 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 36 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 Sutent 50mg capsule (Pfizer Laboratories) 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	HDPE bottle (each contains 28 capsules)
	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 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 36 months

Evaluation by PEC:

Sr.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid certificate of Good Manufacturing Practices of drug product manufacturer, since the submitted document has been expired in 2021.	Firm submitted the GMP certificate no. DA/6-110/06/6751 dated 23rd March,2023 issued by Directorate General of Drug Administration, Dhaka, Bangladesh and valid for 2 years.
2.	Submit data of analytical Method verification studies under section 3.2.S.4 including specificity, accuracy and repeatability (method precision) since you have submitted validation studiesGC method for determination of residual solvent of Sunitinib Malate.	Firm submitted the analytical verification data of drug substance.
3.	Scientific justification is required that how your applied product be equivalent to innovator product as the sutent brand is the capsule filled with granules, while the applied product is the capsule filled with dry powder mixture of active material and excipient.	Firm replied that as per *GUIDELINE THE INVESTIGATION OF BIOEQUIVALENCE* (Doc. Ref.: CPMP/EWP /QWP/1 401/98 Rev. 1/ Corr**) (EMA guidelines) Medicinal products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the

		same dosage forms that meet the same or comparable standards. We have manufactured Sunitix Capsule is identical as oral capsule dosage form as reference product (Sutent Capsule). Sunitix Capsulecontains Sunitinib Malate equivalent Sunitinib which is identical Sutent Capsule which contains Sunitinib Malate equivalent Sunitinib. An open label, balanced, randomized, two-treatment, two-sequence, two- period, crossover oral bioequivalence study of single dose of Sunitix Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Beacon Pharmaceuticals Limited with Sutent Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Pfizer Limited already performed. There was no serious adverse effect reported during study period & clinically safe as a single oral dose administration. Based on Pharmacokinetic Variables & statistical evaluation, it was observed that for both the test & reference product are bioequivalent.	
4.	*According to the FDA's Dissolution guidance document 2018 (same document has been referred for innovator product) the standard dissolution testing condition for sunitinib malate capsule should be "Paddle Method (USP apparatus 2) • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C". While the dissolution medium specified by the drug product manufacturer under section 3.2.P.2 and 3.2.P.5.2 was different from the said FDA's guidance document in term of use of surfactant. Scientific justification is required for using different dissolution medium from that of innovator product approved in USFDA.* *Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes in light of FDA dissolution database and innovator product's review literature. Since the acceptance criteria as per the FDA dissolution database refer to FDA's dissolution guidance 2018 in which it is recommended that "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes", further, the innovator product approved in FDA also recommend Q at 30 minutes.* Firm submitted the revised dissolution with the claimed of in line to innovator product sutent capsule of USFDA along with revised CDP report.		
	Dissolution condition of applied product	Dissolution condition of Innovator's Formulation	
	Apparatus USP II (Paddle System) Dissolution medium: 0.1N HCl Volume: 900ml RPM: 50 Temperature: 37°C ± 0.5°C Dissolution Time: 30 minutes Acceptance Criteria: NLT 80% of thelabeled amount of sunitinib is dissolved in 30 minutes.	Apparatus USP II (Paddle System) Dissolution medium: 0.1M HCl Volume: 900ml Temperature: 37°C ± 0.5°C Dissolution acceptance criteria : NLT Q in 30 minutes.	
5.	All quality test which have been included in the finished product specification was not performed during pharmaceutical equivalence studies, clarification is required in this regard.	Firm submitted the revised pharmaceutical equivalence report in which all the quality test was included in line with drug product specification.	
6.	Assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt form or its base form. While the acceptance	Firm submitted the revised pharmaceutical equivalence report in which the assay limit is specified both in percentage and in mg.	

	criteria specified in the finished product specification was content of sunitinib per capsule i.e.45.0mg to 55.0m.Justification is required regarding the disparity in acceptance criteria of assay of drug product in various sections.		
7.	Detailed analytical method validation report is required mentioning the concentration of test solutions and their individual results along with the results of mean value.	Firm has submitted the revised analytical method validation for drug product.	
8.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted	

Decision: Deferred for submission of performance report of dissolution test in accordance with revised dissolution procedure and acceptance criteria.

441.	Name, address of Applicant / Importer	M/s: Sohail Corporation Address: Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan.
	Details of Drug Sale License of importer	License No: 239 Address: Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan. Address of Godown: NA Validity: 18-Nov-2027 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale.
	Name and address of marketing authorization holder (abroad)	M/s Shandong Hualu Pharmaceutical Co., Ltd. Address: No.1 Hualu Road Chipping Country, Shandong Province, China.
	Name, address of manufacturer(s)	M/s Shandong Hualu Pharmaceutical Co., Ltd. Address: No.1 Hualu Road Chipping Country, Shandong Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No: 202100723(1) Dated 07-04-2021 issued by The first branch of regional Inspection of Shandong Drug Administration for Sodium Chloride Injection 0.9g/100ml. 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. Also, firm has submitted GMP certificate no. SD20190868 valid till 18-02-2024.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of Sole Agency Agreement from Shandong Hualu Pharmaceutical Co., Ltd. The letter specifies that the manufacturer appoints M/s Sohail Corporation to register their products in Pakistan. This agreement is valid till 25-12-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 28165 dated 04-10-2022
	Details of fee submitted	Rs.150,000/- dated 23-09-2022
	The proposed proprietary name / brand name	0.9% Sodium Chloride Injection 100ml.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Each 100ml water contains Sodium Chloride …. 0.9g
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	API: Sodium Chloride Therapeutic classification: Electrolyte supplements (deficiency.) ATC code: B05XA03
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	In one carton 80 bottles of 100ml
	Proposed unit price	Rs 70/- per single bottle
	The status in reference regulatory authorities	Normasil 0.9% (TGA Approved).
	For generic drugs (me-too status)	Not confirmed in 100ml.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shandong Feicheng Refined Salt Plant Address of the manufacturer (s): No.002, Feicheng City, Shandong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted Pharmaceutical Equivalence studies report
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Sodium Chloride Injection is supplied in Polypropylene infusion bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 3 batches is for 36 months

Evaluation by PEC:

Section no.	Observation	Firm's response
3.2.S.4	Analytical method verification studies for the drug substance shall be submitted from the drug product manufacturer.	Firm submitted the analytical verification report of assay of drug substance performed by drug product manufacturer.
3.2.P.2.2.1	Pharmaceutical equivalence against the innovator drug product shall be submitted.	Firm has submitted the comparison table of critical quality attributes between self-developed formulation of M/s. Shandong Hualu Pharmaceutical Co. Ltd and Reference Listed Drug (name of manufacturer and batch detail is not mentioned). Equivalence report did notinclude the test of Iron, test of particulate matter in injection and Bacterial Endotoxin test as per USP monograph.

Decision of 330th meeting of Registration Board:
Deferred for submission of details of Reference Listed product including name, manufacturing date, expiry date etc. against which pharmaceutical equivalence is submitted

Response of the Firm:
Firm submitted the response that they performed pharmaceutical equivalence against the three batches of sodium chloride injection of M/s. Baxter Healthcare Co. Ltd. , Shanghai that are S1910133 (Mfg date :13-10-2019 Exp date: 12-10-2022),S1910134(Mfg date :13-10-2019 Exp date: 12-10-2022),,S1910135 (Mfg date :13-10-2019 Exp date: 12-10-2022).

Decision: Approved as per inspection policy for manufacturer abroad.

442.	Name, address of Applicant / Importer	M/s. VIZ Remedies Pakistan LLP
	Details of Drug Sale License of importer	License No. 1174 Address: Suit No.26 4th Floor Kehkashan Mall, Tariq Road. Block-2 PECHS Karachi Address of Go down: NA Validity: 13-02-2022 Status: License to sell drugs as distributor Renewal: Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name, address of manufacturer(s)	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name of exporting country	China

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted copy of CoPP certificate (No: 20200029) dated 16-06-2020 issued by Shaanxi ProvincialDrug Administration. 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. Furthermore, the CoPP was valid till 15-06-2022. Copy of GMP certificate of M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. is submitted which was valid till 22-09-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Exclusive Marketing Agreement between M/s. VIZ Remedies Pakistan LLP and M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. The letter specifies that the manufacturer appoints M/s. VIZ Remedies Pakistan LLP. Is their exclusive agent 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. 24063 : dated 01-09-2021
	Details of fee submitted	PKR 100,000/-: dated 18-01-2021 (Differential fee of Rs. 50,000/- is to be submitted by the firm)
	The proposed proprietary name / brand name	Tirofiban Hydrochloride Injection 5mg/100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100mL contains: Tirofiban Hydrochloride (calculated based on Tirofiban)5mg
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Anti-Platelet
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x100ml neutral borosilicate glass infusion bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (AGGRASTAT Injection)
	For generic drugs (me-too status)	Not confirmed in the applied volume i.e.100ml
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of Tirofiban hydrochloride Injection instead of Tirofiban hydrochloride 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, containerclosure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence study has been performed against the innovator product AGGRASTAT Injection (Batch no. C856260) which includes quality test (Appearance, pH , Assay, Citric Acid and sodium citrate content, sodium chloride content and related substance test.)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	100ml- neutral borosilicate glass Infusion bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 following batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. B171001,B171002,B171003

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.3	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.
2.	1.4	Submit valid drug sale license of VIZ Remedies Pakistan LLP ,since you have submitted the expired DSL.
3.	3.2.S.7	Submit stability data of three batches of drug substance performed at long term stability conditions till the claimed re-test date since you have submitted the data of only 12 months.
4.	3.2.P.3	Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.
5.	3.2.P.5.1	Justify how the labelled amount of tirofiban will be quantify, since the assay method given in section 3.2.P.5.2 calculate the quantity of tirofiban hydrochloride instead of labelled quantity of tirofiban without the salt factor.
6.	3.2.P.5.4	Justify for using the excipient sodium chloride in the product name along with tirofiban hydrochloride.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.	Firm replied that they submitted original and legalized CoPP at the time of registration. However due to its expiration, renewed CoPP has been requested to the principal manufacturer.
2.	Submit valid drug sale license of VIZ Remedies Pakistan LLP ,since you have submitted the expired DSL.	Firm submitted the copy of DSL no. 0324 which is valid till 14/03/2028.
3.	Submit stability data of three batches of drug substance performed at long term stability conditions till the claimed re-test date since you have submitted the data of only 12 months.	Firm submitted the stability data of 36 months of three batches performed at long term conditions.
4.	Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.	Firm in their reply submitted a document, which only stated the quality parameters used for the analysis of activated charcoals INSTEAD of providing reference from international standard to rationalize the use of activated charcoal for sterilizing the injectable solution..
5.	Justify how the labelled amount of tirofiban will be quantify, since the assay method given in section 3.2.P.5.2 calculate the quantity of tirofiban hydrochloride instead of labelled quantity of tirofiban without the salt factor.	Firm clarify that they quantify the quantity of tirofiban by using external standard method, the obtained assay is for tirofiban hydrochloride, then the results will multiply by conversion coefficient (0.8899) to obtain labelled amount of Tirofiban.
6.	Justify for using the excipient sodium chloride in the product name along with tirofiban hydrochloride.	Firm replied that the role of sodium chloride in this formulation is as "Osmotic Pressure Modifier".

Decision: Deferred for submission of following shortcomings:

- **Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.**
- **Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.**

b. Cases of Locally Manufactured Product

443.	Oral liquid syrup section (general) is approved vide letter No. F. 1-25/2008-Lic dated 17-09-2021.	
	Name, address of Applicant / Marketing Authorization Holder	M/s. World Biz Pharmaceutical Company Plot No. 340, Multan Industrial Estate, Multan.
	Name, address of Manufacturing site.	M/S World Biz Pharmaceutical Company Plot No. 340, Multan Industrial Estate, Multan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.706 : dated 09-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 67913763 dated 03-01-2023.
	The proposed proprietary name / brand name	SetBiz 5mg/5ml syrup.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cetirizine dihydrochloride 5mg (B.P Specifications)
	Pharmaceutical form of applied drug	Oral liquid.
	Pharmacotherapeutic Group of (API)	R06AE07 Antihistamine
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	60ml,90ml,120ml,450ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA APPROVED
	For generic drugs (me-too status)	Citzin Syrup, NovaMed Pharmaceuticals, Reg. No. 063620.
	GMP status of the Finished product manufacturer	New license issued dated 14-09-2021 w.e.f. 13-09-2021.
	Name and address of API manufacturer.	Oral liquid syrup section (general) is approved vide letter No. F. 1-25/2008-Lic dated 17-09-2021.
	Module-II (Quality Overall Summary)	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.
	Module III (Drug Substance)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Stability studies	Official monograph of Cetirizine Hydrochloride is present in B.P. Firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions.

		The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. Batches:(CZ/V/00411,CZ/V/00511& CZ/V/00611)
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Pharmaceutical Equivalence is established against the Citzin syrup manufactured by NovaMed pharmaceuticals Lahore by performing quality tests (Identification, filled volume, leakage teat, pH and Assay).Results of both the products are similar. CDP is not applicable.

STABILITY STUDY DATA			
Manufacturer of API	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.		
API Lot No.	CTZ03521		
Description of Pack (Container closure system)	An amber glass bottle containing an-off white colored syrupy liquid with pleasant flavour, sealed with aluminum pp cap and packed in specific unitcarton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-CS-001	RD-CS-001	RD-CS-001
Batch Size	500 bottles.	500 bottles.	500 bottles.
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	28-09-2022.	28-09-2022.	28-09-2022.
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted copy of approval of PolyBiz syrup in 322 minutes of meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate #L.Dis.No:82408/TS/2022 issued by Drug Control Administration Government of Telangana issued on 15-03-2022and valid until 14-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that the cetirizine dihydrochloride material of quantity 500g was obtained via loan from British Pharmaceuticals Lahore. Copy of documentsalready submitted in DRAP on dated 14-02-2023. • Copy of Form 3, 5 ,7 from & invoice (invoice# ZHI-CI/5465/0621) dated: 26-06- 2021 cleared by DRAP Lahore office dated 12-07-2021

		specifying import 100Kg Cetirizine 2HCl(Batch# CTZ03521)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summarydata sheets etc
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.7	Justify for not including the test of pH determination and loss on drying test while performing the stability studies of drug substance.
2.	3.2.P.1	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
3.	3.2.P.2.2.1	Justify for performing the pharmaceutical equivalence against the comparator product instead of brand leader/ innovator / reference product.
4.	3.2. P.4	Submit the analysis report/COA of excipients propylene glycol and sorbitol, which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide No. F.6-30/2022-QA dated 21-10-2022.
5.	3.2.P.5.2	Justify for not adopting the assay procedure as recommended in BP monograph of Cetirizine Oral solution, since the conc. of sample and standard solution specified in the assay method is different from the concentrations of solution mentioned in BP. Further the validation studies were also performed keeping the conc. of sample and standard solution 0.1% while BP recommends 0.002% conc. for both solutions in assay testing, then justify how the method comply BP specification.
6.	3.2.P.8	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Approval of API/ DML/ valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision of 327th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	3.2.S.7	Justify for not including the test of pH determination and loss on drying test while performing the stability studies of drug substance.	Firm replied that pH and Loss on Drying test is included in the specification and routine testing but by the manufacturer this test was skipped during stability studies of drug substance.
2.	3.2.P.1	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted preservative effectiveness test report.
3.	3.2.P.2.2.1	Justify for performing the pharmaceutical equivalence against the comparator product instead of	Firm replied that comparative product sample was available at that time of trial

			brand leader/ innovator / reference product.	batch manufacturing, so they use that sample for pharmaceutical equivalence.	
	4.	3.2. P.4	Submit the analysis report/COA of excipients propylene glycol and sorbitol, which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide No. F.6-30/2022-QA dated 21-10-2022.	COAs of propylene glycol and sorbitol in which results of impurity test of DEG and EG is included.	
	5.	3.2.P.5.2	Justify for not adopting the assay procedure as recommended in BP monograph of Cetirizine Oral solution, since the conc. of sample and standard solution specified in the assay method is different from the concentrations of solution mentioned in BP. Further the validation studies were also performed keeping the conc. of sample and standard solution 0.1% while BP recommends 0.002% conc. for both solutions in assay testing, then justify how the method comply BP specification.	Firm replied that "All chromatographic conditions as described in BP monograph was followed for the testing of product, sample and standard concentration was set for the easiness for the analyst and method was verified on the same concentration was set for the easiness for the analyst and method was verified on the same concentration as well.	
	6.	3.2.P.8	Submit the updated stability data of drug product, since you have submitted only three-month stability data.	Submitted	
	7.	Approval of API/ DML/ valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Firm submitted the copy of letter by DCA (Government of Telangana) in which it is certified that License No. 40/MD/AP/2012/B/G renewed 18/10/2022 and validity would get expired by 17/10/2027.	

Decision: Deferred for submission of following:

- **Scientific justification for not performing critical tests of pH determination and loss on drying during the stability studies.**
- **Justification for not performing the assay of drug product in accordance with BP monograph of Cetirizine Oral solution.**

M/s. Winbrains Research Laboratories Plot no.69/1 Block B, Phase I-II, Industrial Estate, Hattar
The Central Licensing Board in its 282nd meeting held on 31st August, 2021 has considered and approved the grant of additional section of "Dry Powder Inhaler Capsule section (General)" to M/s. Winbrains Research Laboratories Plot no.69/1 Block B, Phase I-II, Industrial Estate, Hattar.

444.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32464 dated 11/11/2022
	Details of fee submitted	PKR 30,000/-:dated 19/10/2022
	The proposed proprietary name / brand name	**Flutimet 100/50mcg Rota Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluticasone Propionate……100mcg Salmeterol Xinafoate 50mcg
	Pharmaceutical form of applied drug	White to off white color powder filled in hard gelatin capsule shells
	Pharmacotherapeutic Group of (API)	Long Acting- Beta agonists Corticosteroids
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved ADVAIR DISKUS 100/50
	For generic drugs (me-too status)	Seretide Diskus 100mcg + 50Mcg GSK Pakistan. (Reg.no.074726)
	GMP status of the Finished product manufacturer	New section approval letter granted on 20/09/2021 (Dry Powder Inhaler and Nasal Drops) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd. Address: A-14/15, MIDC Area, Chincholi, Solapur, 413255Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of both drug substances are present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physicalform, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Fluticasone Propionate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(FTP0010414,FTP-0020715,FTP-0010615) Salmeterol Xinafoate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

		Batches: (SX-0020515,SX-0030515,SX-0040515)
	Module-III (Drug Product):	The firm has submitted description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence report has not submitted by the firm.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Flutimet Turbo haler is an inspiratory flow driven,multidose powder inhaler.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vamsi Labs Ltd. Address: A-14 & 15, MIDC Area, Chincholi, Solapur, Maharashtra 413255, India		
API Lot No.	Firm has not mentioned the API lot no. of both drug substances.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-46	T-47	T-48
Batch Size	500 Capsule	500 Capsule	500 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	25-12-2021	25-12-2021	25-12-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.
2.	3.2.S.4.1-3.2.S.4.2	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
3.	3.2.S.4.3	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.
4.	3.2.S.4.4 (Fluticasone)	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph. Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.
5.	3.2.S.7.3 (Salmetrol Xinafoate)	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.
6.	3.2.P.1	• Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules. • Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcgof salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins). • Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
7.	3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.
8.	3.2.P.2.3	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
9.	3.2.P.5.2	• Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph. • Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.
10	3.2.P.5.3	Provide analytical method verification report of drug product in compliance of USP monograph.

11	3.2.P.5.4	• Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. • Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.	
12	3.2.P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.	
13	3.2.P.8	• Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. • Provide Reference of previous approval of applications with stability study data of the firm (if any) • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	
14	2.3 R.1.1	• Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. • Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR,please provide the calculations.	

Decision of 323rd meeting of Registration Board:
Deferred for submission of reply of above-cited shortcomings within six month.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.	Firm submitted the revised specification of drug product but microbial enumeration test ,test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.
2.	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only	Firm only submitted the specification and analytical procedure of drug substance by drug substance manufacturer but did not submitted the specification and analytical procedure of drug substance adopted by drug product manufacturer.

		submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.		
	3.	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.	Firm did not submit the response of this query.	
	4.	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph.	Firm only submitted the revised COAs of drug substance in which results of Optical rotation test included.	
	5.	Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.	Firm did not submit the response of this query.	
	6.	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.	Submitted	
	7.	Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.	Firm replied that their inhaler device is consist of three components included mouthpiece, rotacap chamber and base.	
	8.	Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins).	Firm submitted the revised composition of drug product in accordance with innovator product.	
	9.	Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration). Firm submitted the following table data in their reply:		

		<table><tr><td>API</td><td>Innovator Spec.</td><td>Winbrains spec.</td></tr><tr><td>Fluticasone propionate</td><td>92 micrograms/inhalation delivered</td><td>90 micrograms/inhalation delivered</td></tr><tr><td>Salmeterol Xinafoate</td><td>47 micrograms/inhalation delivered</td><td>46 micrograms/inhalation delivered</td></tr></table>			
	10.	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.	Firm submitted the pharmaceutical equivalence report against the Seretide Diskus 50/100mcg Powder for inhalation *(The inhalation powder is contained in blisters held on a formed PVC coated base, with a peelable foil laminate lid. The strip is contained in a moulded plastic device. The plastic devices are available in cardboard containers, which hold)* (Batch no.170930 Mfg date: 05-2021 and Expiry date: 04-2024), while firm in its report described the reference product as *white capsule orange body hard gelatin capsule shell no.3 filled with white to off white color powder.* Further, microbial enumeration test ,test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted report.	
	11.	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.	Not submitted the response of this query.		
	12.	Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph.	Firm		
	13.	Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.	Firm submitted the revised specification including the performance tests.		
	14.	Provide analytical method verification report of drug product in compliance of USP monograph.	Not submitted the reply of this query		
	15.	• Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter	Not submitted the reply of this query		

		test while batch releaseof drug product. • Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.		
	16.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Not submitted the reply of this query	
	17.	• Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Not submitted the reply of this query	
	18.	Provide details that whichlot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of commercial invoice without attestation from DRAP.	
	19.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Not submitted the reply of this query	

	20.	Provide Reference of previous approval of applications with stability study data of the firm (ifany)	Not submitted the reply of this query	
	21.	Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted	
	22.	• Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. • Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please providethe calculations.	Not submitted the reply of this query	

Decision: Deferred for submission of reply to following shortcomings:

- **Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.**
- **Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer, since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.**
- **Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.**
- **Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.**
- **Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.**
- **Provided details regarding the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration) are different from that of innovator drug product.**
- **Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted Pharmaceutical equivalence report.**
- **Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.**
- **Provide analytical method verification report of drug product in compliance of USP monograph.**
- **Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.**
- **Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.**
- **Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.**
- **Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.**

• **Provide certificate of analysis of reference standard /working standard used for testing of the product.** • **Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product.** • **Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.** • **Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.** • **Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.** • **Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.** • **Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.**		
445.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32465 dated 11/11/2022
	Details of fee submitted	PKR 30,000/-:dated 19/10/2022
	The proposed proprietary name / brand name	Flutimet 250/50mcg Rota Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluticasone Propionate……250mcg Salmeterol Xinafoate..... 50mcg
	Pharmaceutical form of applied drug	White to off white color powder filled in hard gelatin capsule shells
	Pharmacotherapeutic Group of (API)	Long Acting- Beta agonists Corticosteroids
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved ADVAIR DISKUS 100/50
	For generic drugs (me-too status)	Seretide Diskus 250mcg + 50mcg GSK Pakistan. (Reg.no.074727)
	GMP status of the Finished product manufacturer	New section approval letter granted on 20/09/2021 (Dry Powder Inhaler and Nasal Drops) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd. Address: A-14/15, MIDC Area, Chincholi, Solapur, 413255Maharashtra, India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of both drug substances are present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Fluticasone Propionate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(FTP0010414,FTP-0020715,FTP-0010615) Salmeterol Xinafoate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (SX-0020515,SX-0030515,SX-0040515)
	Module-III (Drug Product):	The firm has submitted description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence report has submitted against the brand leader seretide Rotacaps 250/50mcg of M/s. Glaxo Smith Kline B.no. R102 Exp date 11-2023 (Identification,assay)
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Flutimet Turbo haler is an inspiratory flow driven,multidose powder inhaler.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vamsi Labs Ltd. Address: A-14 & 15, MIDC Area, Chincholi, Solapur, Maharashtra 413255, India
API Lot No.	Firm has not mentioned the API lot no. of both drug substances.
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-49	T-50	T-51
Batch Size	500 Capsule	500 Capsule	500 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	25-12-2021	25-12-2021	25-12-2021
No. of Batches	03		

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

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.
2.	3.2.S.4.1-3.2.S.4.2	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
3.	3.2.S.4.3	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.
4.	3.2.S.4.4 (Fluticasone)	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph. Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer,since it was evident from the batch analysis report that you have performed Particle size test by Malvern.
5.	3.2.S.7.3 (Salmetrol Xinafoate)	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.

6.	3.2.P.1	• Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules. • Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins). • Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).	
7.	3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference productshall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.	
8.	3.2.P.2.3	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.	
9.	3.2.P.5.2	• Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph. • Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.	
10.	3.2.P.5.3	Provide analytical method verification report of drug product in compliance of USP monograph.	
11.	3.2.P.5.4	• Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. • Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.	
12.	3.2.P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.	
13.	3.2.P.8	• Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. • Provide Reference of previous approval of applications with stability study data of the firm (if any) • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	
14.	2.3 R.1.1	• Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. • Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR,please provide the calculations.	

15.	Amendment in QOS (Module 2) for above points.	

Decision of 323rd meeting of Registration board:
Deferred for submission of reply of above-cited shortcomings within six month.

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.	Firm submitted the revised specification of drug product but microbial enumeration test ,test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.
2.	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.	Firm only submitted the specification and analytical procedure of drug substance by drug substance manufacturer but did not submitted the specification and analytical procedure of drug substance adopted by drug product manufacturer.
3.	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.	Firm did not submit the response of this query.
4.	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph.	Firm only submitted the revised COAs of drug substance in which results of Optical rotation test included.
5.	Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis	Firm did not submit the response of this query.

<table>
<tr><td></td><td></td><td>report that you have performed Particle size test by Malvern.</td><td></td><td></td></tr>
<tr><td></td><td>6.</td><td>Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.</td><td>Submitted</td><td></td></tr>
<tr><td></td><td>7.</td><td>Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.</td><td>Firm replied that their inhaler device is consist of three components included mouthpiece, rotacap chamber and base.</td><td></td></tr>
<tr><td></td><td>8.</td><td>Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins).</td><td>Firm submitted the revised composition of drug product in accordance with innovator product.</td><td></td></tr>
<tr><td></td><td>9.</td><td colspan="2">Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
Firm submitted the following table data in their reply:
<table>
<tr><td>API</td><td>Innovator Spec.</td><td>Winbrains spec.</td></tr>
<tr><td>Fluticasone propionate</td><td>92 micrograms/inhalation delivered</td><td>90 micrograms/inhalation delivered</td></tr>
<tr><td>Salmeterol Xinafoate</td><td>47 micrograms/inhalation delivered</td><td>46 micrograms/inhalation delivered</td></tr>
</table></td><td></td></tr>
<tr><td></td><td>10.</td><td>Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation.
Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.</td><td>Firm submitted the pharmaceutical equivalence report against the Seretide Diskus 50/100mcg Powder for inhalation (The inhalation powder is contained in blisters held on a formed PVC coated base, with a peelable foil laminate lid. The strip is contained in a moulded plastic device. The plastic devices are available in cardboard containers, which hold) (Batch no.170930 Mfg date: 05-2021 and Expiry date: 04-2024), while firm in its report described the reference product as white capsule orange body hard gelatin capsule shell no.3 filled with white to off white color powder.
Further, microbial enumeration test ,test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted report.</td><td></td></tr>
<tr><td></td><td>11.</td><td>Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm,</td><td>Not submitted the response of this query.</td><td></td></tr>
</table>

		please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.		
	12.	Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph.	Firm submit the analytical procedure of drug product.	
	13.	Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.	Firm submitted the revised specification including the performance tests.	
	14.	Provide analytical method verification report of drug product in compliance of USP monograph.	Not submitted the reply of this query	
	15.	• Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. • Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.	Not submitted the reply of this query	
	16.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Not submitted the reply of this query	
	17.	• Justify for not performing the test	Not submitted the reply of this query	

		Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.		
	18.	Provide details that which lot number ofdrug substance has beenused in manufacturing ofeach batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the copy of commercial invoice without attestation from DRAP.	
	19.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Not submitted the reply of this query	
	20.	Provide Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted the reply of this query	
	21.	Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted	
	22.	• Manufacturing procedure mentioned in BMR is different from the manufacturing	Not submitted the reply of this query	

		procedure given in 3.2.P.3, justification is required in this regard. • Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.		

Decision: Deferred for submission of reply to following shortcomings:

- **Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the finished product specification.**
- **Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer, since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.**
- **Submit data for "Analytical Method Verification studies" including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.**
- **Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer, since it was evident from the batch analysis report that you have performed Particle size test by Malvern.**
- **Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules.**
- **Provided details regarding the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration) are different from that of innovator drug product.**
- **Microbial enumeration test, test for specified microorganism, foreign particulate matter and Delivered Dose Uniformity test was not included in the submitted Pharmaceutical equivalence report.**
- **Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.**
- **Provide analytical method verification report of drug product in compliance of USP monograph.**
- **Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.**
- **Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.**
- **Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product.**
- **Provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.**
- **Provide certificate of analysis of reference standard /working standard used for testing of the product.**
- **Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product.**
- **Justify for performing the pharmaceutical equivalence against the product Seretide Diskus Powder for inhalation, when the applied product is rotacaps**
- **Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.**
- **Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**

	• **Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.** • **Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard.** • **Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR, please provide the calculations.**	
446.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceuticals 23 km Sheikhupura road-Lahore Pakistan.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals 23 km Sheikhupura road-Lahore Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML granted on 13-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying oral dry powder for suspension (Penicillin),Capsule(Penicillin), Tablet (Penicillin), Dry powder injectable(Penicillin),Dry powder injectable(Carbapenem) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.no. 8956 dated 03-04-2023
	Details of fee submitted	PKR 30,000/- Dated 16-03-2023
	The proposed proprietary name / brand name	Flepicin 125 mg/5mL Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Phenoxy methyl penicillin potassium eq to Phenoxy methyl penicillin…… 125mg
	Pharmacotherapeutic Group of (API)	penicillin antibiotics
	Pharmaceutical form of applied drug	White to off white well homogenized powder free from extraneous matter filled in ambered glass bottle sealed with flip and pp cap neatly labelled and packed in a unit carton with insertion of a leaflet, plastic measuring cup 20 mL and plastic spoon 5 mL on reconstitution with 40 mL of water off white suspension with sweet taste is availed.
	Reference to Finished product specifications	BP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Phenoxymethylpenicillin 125 mg Suspension (MHRA Approved)
	For generic drugs (me-too status)	Penicillin V Suspension of M/s. Lisko Pakistan Pvt. Ltd. Karachi, Reg.no. 006464
	Name and address of API manufacturer.	Hebei North China Pharmaceutical Huaheng Pharmaceutical Co., Ltd. Xingwang Road, Biological Industry Zone,

		Nanbaishe Town, Zhao County, Shijiazhuang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the generic product Penicillin V Suspension 125 mg manufactured by Elite Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Hebei North China Pharmaceutical Huaheng Pharmaceutical Co., Ltd.		
API Lot No.	20062105043		
Description of Pack (Container closure system)	FPP is packed in ambered colored glass bottle, further packed in unit carton along with patient leaflet insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	700 Units	700 Units	700 Units
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	29-04-2022	29-04-2022	29-04-2022

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Flemicillin Capsule 250 mg (322th Meeting) Flemicillin Capsule 500 mg (322th Meeting) F-Amox Suspension 125mg/5mL (323rd Meeting) F-Amox Suspension 250 mg/5mL (323rd Meeting) Fletazo Injection 2.25 g (323rd Meeting) Fletazo Injection 4.50 g (323rd Meeting) Flementin Injection 1200 mg (324th Meeting) Flementin Injection 600 mg (324th Meeting)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. Yi 20180010) dated 23-09-2021 issued By Hebei Province Drug Administration China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 27-01-2022 specifying 25.0 Kg of Phenoxymethyl penicillin Potassium. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will besupported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	
1.	3.2.P.1	Formulation contain preservative sodium benzoate, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted the Antimicrobial Effectiveness test report with theremarks that sodium Benzoate iseffective for use in oral product, while the antimicrobial effectiveness test should be performed specifically on the applied product.
2.	3.2.P.1	Provide information including type of diluent, its composition, quantity or volume which is to be provided along with the applied drug.	Firm replied that Diluent to be used for reconstitution is water. Direction for reconstitution is as: Add 30 mL water and shake well than add again 30 mL water to produce 100 mL solution.
3.	3.2.P.2.2 .1	Specify Product name and Registration number of reference product against which pharmaceutical equivalence has been established.Further,Justify why the pharmaceutical equivalence was studied against comparator product instead of using innovator / reference product.	Firm replied that Pharmaceutical Equivalence study is performed against comparator product penicillin V manufactured by Elite pharmaceutical with registration number 001852. However, the registration status of comparator product against which the pharmaceutical equivalence has established was not confirmed from the available registered data.

	4.	3.2.P.7	Please specify the volume size of ambered glass bottle used to fill the suspension since you have not mentioned the volume size in the requisite section.	Firm replied that Volume size of ambered glass bottle used to fill the suspension is 120 mL.	
	5.	3.2.P.8	Chromatograms and audit trail reports of phenoxymethyl penicillin tablets has been attached in the dossier of suspension. Clarification is required in this regard.	Firm replied that We started working simultaneous on both products i.e Flepicin Suspension (Phenoxymethylpenicillin Potassium) and Flepicin Tablets (Phenoxymethylpenicillin Potassium) and during binding of Flepicin Suspension dossier, chromatograms and audit trail reports of phenoxymethyl penicillin tablets were attached. Now we have attached Chromatograms and audit trail reports of phenoxymethyl penicillin Suspension with this letter	
	6.	3.2.P.8	In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.	Firm replied that in-use stability study has already been conducted and data has been attached in ANNEX III. However, Annexure-III is not attached in the submitted reply.	

Decision of 330th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit product specific preservative effectiveness studies performed in accordance with USP General Chapter <51>.
- In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.

Response of the Firm:

- Submit product specific preservative effectiveness studies performed in accordance with USP General Chapter <51>.

Firm submitted the Antimicrobial Effectiveness report of drug product, performed in accordance with USP General Chapter <51>.

- In-use stability studies of reconstituted suspension are required along with proposed in-use storage statement and in-use shelf-life.

Firm submitted the in-use stability data of reconstituted suspension, performed at refrigerated condition and with the conclusion that "reconstituted suspension found to be stable for 14 days.

Decision: Approved.

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

447.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceuticals 23 km Sheikhupura road- Lahore Pakistan.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals 23 km Sheikhupura road- Lahore Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML granted on 13-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying oral dry powder for suspension

		(Penicillin),Capsule(Penicillin), Tablet (Penicillin), Dry powder injectable(Penicillin),Dry powder injectable(Carbapenem) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.no. 8957 dated 03-04-2023
	Details of fee submitted	PKR 30,000/- Dated 16-03-2023
	The proposed proprietary name / brand name	Flepicin 250 mg/5mL Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Phenoxy methyl penicillin potassium eq to Phenoxy methyl penicillin…… 250mg
	Pharmacotherapeutic Group of (API)	penicillin antibiotics
	Pharmaceutical form of applied drug	White to off white well homogenized powder free from extraneous matter filled in ambered glass bottle sealed with flip and pp cap neatly labelled and packed in a unit carton with insertion of a leaflet, plastic measuring cup 20 mL and plastic spoon 5 mL on reconstitution with 60 mL of water off white suspension with sweet taste is availed.
	Reference to Finished product specifications	BP
	Proposed Pack size	1’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Phenoxymethylpenicillin 250 mg Suspension (MHRA Approved)
	For generic drugs (me-too status)	Penicillin VK-DS Dry Suspension of M/s. Lisko Pakistan Pvt. Ltd. Karachi, Reg.no. 070542
	Name and address of API manufacturer.	Hebei North China Pharmaceutical Huaheng Pharmaceutical Co., Ltd. Xingwang Road,Biological Industry Zone, Nanbaishe Town, Zhao County, Shijiazhuang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, generalproperties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the generic product Penicillin V Suspension 250 mg manufactured by Elite Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Hebei North China Pharmaceutical Huaheng Pharmaceutical Co., Ltd.		
API Lot No.	20062105043		
Description of Pack (Container closure system)	FPP is packed in ambered colored glass bottle, further packed in unit carton along with patient leaflet insert.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	700 Units	700 Units	700 Units
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	29-04-2022	29-04-2022	29-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Flemicillin Capsule 250 mg (322th Meeting) Flemicillin Capsule 500 mg (322th Meeting) F-Amox Suspension 125mg/5mL (323rd Meeting) F-Amox Suspension 250 mg/5mL (323rd Meeting) Fletazo Injection 2.25 g (323rd Meeting) Fletazo Injection 4.50 g (323rd Meeting) Flementin Injection 1200 mg (324th Meeting) Flementin Injection 600 mg (324th Meeting)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. Yi 20180010) dated 23-09-2021 issued By Hebei Province Drug Administration China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 27-01-2022 specifying 25.0 Kg of Phenoxymethyl penicillin Potassium. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	
1.	3.2.P.1	Formulation contain preservative sodium benzoate, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted the Antimicrobial Effectiveness test report with the remarks that sodium Benzoate is effective for use in oral product, while the antimicrobial effectiveness test should be performed specifically on the applied product.
2.	3.2.P.1	Provide information including type of diluent, its composition, quantity or volume which is to be provided along with the applied drug.	Firm replied that Diluent to be used for reconstitution is water. Direction for reconstitution is as: Add 30 mL water and shake well than add again 30 mL water to produce 100 mL solution.
3.	3.2.P.2.2.1	Specify Product name and Registration number of reference product against which pharmaceutical equivalence has been established.Further,Justify why the pharmaceutical equivalence was studied against comparator product instead of using innovator / reference product.	Firm replied that Pharmaceutical Equivalence study is performed against comparator product penicillin V manufactured by Elite pharmaceutical with registration number 001852. However, the registration status of comparator product against which the pharmaceutical equivalence has established was not confirmed from the available registered data.
4.	3.2.P.7	Please specify the volume size of ambered glass bottle used to fill the suspension since you have not mentioned the volume size in the requisite section.	Firm replied that Volume size of ambered glass bottle used to fill the suspension is 120 mL.
5.	3.2.P.8	Chromatograms and audit trail reports of phenoxymethyl penicillin tablets has been attached in the dossier of suspension. Clarification is required in this regard.	Firm replied that We started working simultaneous on both products i.e Flepicin Suspension (Phenoxymethylpenicillin Potassium) and Flepicin Tablets (Phenoxymethylpenicillin Potassium) and during binding of Flepicin Suspension dossier, chromatograms and audit trail reports of phenoxymethyl penicillin tablets were attached. Now we have attached Chromatograms and audit trail reports of phenoxymethyl penicillin Suspension with this letter
6.	3.2.P.8	In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.	Firm replied that in-use stability study has already been conducted and data has been attached in ANNEX III. However, Annexure-III is not attached in the submitted reply.

Decision of 330th meeting of Registration Board:
Deferred for submission of following shortcomings:

- Submit product specific preservative effectiveness studies performed in accordance with USP General Chapter <51>.
- In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.

Response of the Firm:

- Submit product specific preservative effectiveness studies performed in accordance with USP General Chapter <51>.

Firm submitted the Antimicrobial Effectiveness report of drug product, performed in accordance with USP General Chapter <51>.

- In-use stability studies of reconstituted suspension are required along with proposed in-use storage statement and in-use shelf-life.

Firm submitted the in-use stability data of reconstituted suspension, performed at refrigerated condition and with the conclusion that "reconstituted suspension found to be stable for 14 days.

Decision: Approved.

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

448.	Name, address of Applicant / Marketing Authorization Holder	MEDICRAFT PHARMACEUTICALS (PVT) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Name, address of Manufacturing site.	MEDICRAFT PHARMACEUTICALS (PVT) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Evidence of approval of manufacturing facility	Firm submitted the copy of letter of Licensing Division regarding the grant of additional section of dry powder for Injection (Carbapenem) dated 14th October,2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5 Dy.No 7653 dated 30-05-2019 Rs.20,000/- dated 30-05-2019 Form-5F Dy.No 14522 dated 08-08-2019 Form-5F Dy.No 32154 dated 24-11-2021
	Details of fee submitted	PKR 20,000/-: dated 30-05-2019
	The proposed proprietary name / brand name	Medipenem 500mg injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate) ……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (MERREM 500mg Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 500mg Injection M/s. Pfizer UK)
	For generic drugs (me-too status)	PENRO IV 500mg Injection M/s, Bosch Pharma
	Name and address of API manufacturer.	Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site*:* No. 2003, Shenyan Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the product Meronem Injection 500mg of M/s. Pfizer Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s. Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site*:* No. 2003, Shenyan Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.
API Lot No.	8MT2102165
Description of Pack	Type I glass vial of 20ml packed inunit carton

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ME01	ME02	ME03
Batch Size	2000 vials	2000 vials	2000 vials
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	17-03-2021	17-03-2021	24-03-2021
No. of Batches	03		

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

Evaluation by PEC:

Sr.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer (M/s. Medicraft Pharmaceuticals (Pvt.) Ltd.)"	submitted
2.	Validation of analytical procedures Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. Batch Analysis Report	Submitted
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	Firm submitted the batch analysis report of drug substance by drug product manufacturer.

4.	Submit real time stability study data of three batches of the drug substance as per the conditions of zone IV-A since the submitted stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5%.	Not submitted	
5.	Submit data in section 3.2.P.2.1.2 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "List of all components of the dosage form, and their amount on a per unit basis (including overages*, if any), the function of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications). *Overages are not acceptable unless fully justified* If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride").	Firm submitted the requisite details of section 3.2.P.2.1.2.	
6.	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.	Firm submitted the information related to the diluents.	
7.	Provide information specify the justification of formulation and method of manufacturing. It is important that critical quality attributes(CQAs) and Critical Process Parameters (CPP) shall also be discussed.	submitted	
8.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	submitted	
9.	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm submitted Pharmaceutical equivalence report performed against the product Meronem Injection of M/s. Pfizer Pharmaceuticals.	
10.	Compatibility studies for the dry powder for injections with its diluent shall be performed as per the instructions provided in individual label of the drug product.	Firm submitted the requisite details.	
11.	Submit data in section 3.2.P.2.2.1 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "*The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g.,*	Submitted	

	sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".		
12.	Justify the use of 10ml type-II glass vial for the applied drug product since as per the innovator's product Meropenem for injection is supplied in 20 mL and 30 mL injection vials containing sufficient meropenem to deliver 500 mg or 1 gram for intravenous administration, respectively.	Firm submitted the reply that 20ml glass vial is used for 500mg and 30ml is used for 100mg.	
13.	Provide the composition for the drug substance with clearly indicated the quantity of its base form and quantity of sodium carbonate along with the amount of sodium (as is basis).	Submitted	
14.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	Submitted the master formulation.	
15.	Provide control of critical steps and intermediates for the applied drug product in section 3.2.P.3.4, since the submitted document contains various variation in terms of weight and fill volume and does not cover all the critical steps involved in the manufacturing.	Submitted the requisite information of section 3.2.P.3.4.	
16.	• Variation has been observed regarding the sterilization process of vial in the process validation protocol. Clarification is required either the dry heat has been used for sterilization of vials or sterilized in autoclave. • The process validation protocols did not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard. • The process validation protocols did not define any critical steps, justify how your process validation protocols can be considered acceptable. • In process validation protocol container description specified that Type-I 2ml clear glass vial has been used clarification is required regarding the variation of container closure system of the applied product. • According to the process validation data sheet bulk solution has been prepared after mixing in manufacturing tank while the manufacturing process given in previous sections revealed that ready to fill active material has been imported and only filling of active material in their respective container has been done by drug product manufacturer clarification is required	Firm submitted the revised process validation protocol.	

	regarding this variation of manufacturing procedure.		
17.	• Justify why the test of content of sodium and loss on drying is not mentioned in the specifications of the drug product • Justification is required for including volume variation test in the dry powder injectable product specification. • In section 1.5.6 applicant claimed USP specification for drug product while in - house specification has been claimed in section 3.2.P.5.2 clarification is required in this regard.	Firm submitted the revised specification of drug product in which test of content of sodium and loss on drying is included. Further claimed that they follow USP specification for drug product.	
18.	As per the submitted master formulation 1000mg per vial quantity has been filled while the weight variation limit specified is 1.445gm±3% per vial justification is required regarding the disparity in filled weight of active material.	Firm submitted the revised master formulation along with calculation of filled weight.	
19.	• As per the submitted procedure of assay, sample solution has been prepared in mobile phase in which 50mg of meropenem has been dissolved initially while according to the USP "*Constitute a container of Meropenem for Injection with a volume of water corresponding to the quantity of solvent specified in the labeling, and dilute with water".* Justify how your method could be considered as complying with USP monograph. • The USP monograph under the assay method specifies that sample should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph. • Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer. • Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	Firm submitted the revised analytical procedure in compliance of USP monograph of Meropenem Injection.	
20.	• Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. • Provide the data of verification studies along with the raw data sheet reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.	Submitted	
21.	Scientific justification for not performing the test of sodium content and loss on drying for the analysis of all three batches of drug product.	Firm submitted the batch analysis report	

22.	As per the batch analysis certificate manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while the section approval was granted on 14th October, 2020.Clarification is required regarding the manufacturing of batches prior section approval, further specify where the manufacturing of these batches was carried out.	Firm did not clarify the manufacturing dates of trial batches , since, initially the manufacturing date of trial batches of both 500mg and 1000mg was the year 2019, later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.	
23.	Provide COA of primary / secondary reference standard including source and lot number.	submitted	
24.	Stability Following clarification is required regarding the date of manufacturing of batches for product development and stability studies: • As per the batch analysis certificate, manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while as per stability data sheets same batches has been manufactured on MP01: 03-2021, MP02:04-2021, MP03:05-2021.Clarification is required in this regard.	Firm clarified that the trial batches of 500mg is ME-01,ME-02,ME-03,while the trial batches of 1000mg is MP-01,MP-02,MP-03.	
25.	Justify why the test of content of sodium and loss on drying has not been performed during the stability studies of drug product.	Firm submitted the revised stability data in which both of these tests are included.	
26.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Not submitted	
27.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Submitted	
28.	Provide Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted	
29.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted	
30.	• Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted	
31.	Executed Production Documents Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted	
Decision of 331st meeting of Registration Board: Deferred for submission of following shortcomings:			

- Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.
- Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Response of the Firm:

- Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.

Firm submitted the stability data of three batches of the drug substance as per the zone IV-a conditions.

- Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.

Firm replied that in 2019 their carbapenem section was ready for inspection but the inspection process of our section was under process and during this period we got the raw material on loan basis and processed our trial batches. Later, they were told that it will not be approved because they don't have a section approval letter and proof of import is also required, so they stopped the work on previous trial batches and initiated new studies after the section approval. After section approval we imported the raw material from Shenzhen Haibin Pharmaceuticals China, via DHL.

Further firm claimed that the old stability documents were withdrawn and previous working was nullified so they used the same batch number ME01,ME02,ME03 for 500mg of their new trial batches.

- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Firm replied that the Batch no. 8MT2102165 is used in all three batches of finished product stability, which was imported from China via DHL and DHL invoice has been submitted by the Firm,

The DHL invoices submitted by the firm were not verifiable.

Decision: Deferred for evidence of procurement/import of drug substance with approval of DRAP I&E Office, since the submitted DHL courier receipt is not verifiable.

449.	Name, address of Applicant / Marketing Authorization Holder	MEDICRAFT PHARMACEUTICALS (PVT) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Name, address of Manufacturing site.	MEDICRAFT PHARMACEUTICALS (PVT) Ltd. 126-B Industrial Estate Rd, Hayatabad, Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Evidence of approval of manufacturing facility	Firm submitted the copy of letter of Licensing Division regarding the grant of additional section of dry powder for Injection (Carbapenem) dated 14th October,2020.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5 Dy. No 7654 dated 30-05-2019 Rs. 20,000/- dated 30-05-2019 Form-5F Dy. No 14521 dated 08-08-2019 Form-5F Dy.No 32155 dated 24-11-2021

	Details of fee submitted	PKR 20,000/-: dated 30-05-2019
	The proposed proprietary name / brand name	Medipenem 1000mg injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate) ……1000mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (MERREM 1000mg Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 1000mg Injection M/s. Pfizer UK)
	For generic drugs (me-too status)	PENRO IV 1000mg Injection M/s, Bosch Pharma
	Name and address of API manufacturer.	Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site*:* No. 2003, Shenyan Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the product Meronem Injection 500mg of M/s. Pfizer Pharma.

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

STABILITY STUDY DATA			
Manufacturer of API	M/s. Shenzhen Haibin Pharmaceutical Co., Ltd. Manufacturing Site*:* No. 2003, Shenyan Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.		
API Lot No.	8MT2102165		
Description of Pack (Container closure system)	Type I glass vial of 20ml packed inunit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MP01	MP02	MP03
Batch Size	2000 vials	2000 vials	2000 vials
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	24-03-2021	24-03-2021	24-03-2021
No. of Batches	03		

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

Evaluation by PEC:

Sr.no.	Observations/Deficiencies/ Short-comings	Response of the Firm	
1.	Submit Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer (M/s. Medicraft Pharmaceuticals (Pvt.) Ltd.)"	submitted	

2.	Validation of analytical procedures Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. Batch Analysis Report	Submitted	
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	Firm submitted the batch analysis report of drug substance by drug product manufacturer.	
4.	Submit real time stability study data of three batches of the drug substance as per the conditions of zone IV-A since the submitted stability data of drug substance is conducted at 25°C ± 2°C/60% RH ±5%.	Not submitted	
5.	Submit data in section 3.2.P.2.1.2 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "List of all components of the dosage form, and their amount on a per unit basis (including overages*, if any), the function of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications). *Overages are not acceptable unless fully justified* If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride").	Firm submitted the requisite details of section 3.2.P.2.1.2.	
6.	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.	Firm submitted the information related to the diluents.	
7.	Provide information specify the justification of formulation and method of manufacturing. It is important that critical quality attributes(CQAs) and Critical Process Parameters (CPP) shall also be discussed.	submitted	
8.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	submitted	
9.	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and	Firm submitted Pharmaceutical equivalence report performed against the product Meronem Injection of M/s. Pfizer Pharmaceuticals.	

	the innovator / reference / comparator product shall be submitted and discussed".		
10.	Compatibility studies for the dry powder for injections with its diluent shall be performed as per the instructions provided in individual label of the drug product.	Firm submitted the requisite details.	
11.	Submit data in section 3.2.P.2.2.1 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "*The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".*	Submitted	
12.	Justify the use of 10ml type-II glass vial for the applied drug product since as per the innovator's product Meropenem for injection is supplied in 20 mL and 30 mL injection vials containing sufficient meropenem to deliver 500 mg or 1 gram for intravenous administration, respectively.	Firm submitted the reply that 20ml glass vial is used for 500mg and 30ml is used for 100mg.	
13.	Provide the composition for the drug substance with clearly indicated the quantity of its base form and quantity of sodium carbonate along with the amount of sodium (as is basis).	Submitted	
14.	Justify the master formulation containing 1gm of sterile mixture of Meropenem and sodium carbonate for manufacturing of 1gm meropenem for injection, since the drug substance contains meropenem blended with 6.2% to 7.9% of sodium carbonate (as is basis).	Submitted the master formulation.	
15.	Provide control of critical steps and intermediates for the applied drug product in section 3.2.P.3.4, since the submitted document contains various variation in terms of weight and fill volume and does not cover all the critical steps involved in the manufacturing.	Submitted the requisite information of section 3.2.P.3.4.	
16.	• Variation has been observed regarding the sterilization process of vial in the process validation protocol. Clarification is required either the dry heat has been used for sterilization of vials or sterilized in autoclave. • The process validation protocols did not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard. • The process validation protocols did not define any critical steps, justify how your	Firm submitted the revised process validation protocol.	

	process validation protocols can be considered acceptable. • In process validation protocol container description specified that Type-I 2ml clear glass vial has been used clarification is required regarding the variation of container closure system of the applied product. • According to the process validation data sheet bulk solution has been prepared after mixing in manufacturing tank while the manufacturing process given in previous sections revealed that ready to fill active material has been imported and only filling of active material in their respective container has been done by drug product manufacturer clarification is required regarding this variation of manufacturing procedure.		
17.	• Justify why the test of content of sodium and loss on drying is not mentioned in the specifications of the drug product • Justification is required for including volume variation test in the dry powder injectable product specification. • In section 1.5.6 applicant claimed USP specification for drug product while in - house specification has been claimed in section 3.2.P.5.2 clarification is required in this regard.	Firm submitted the revised specification of drug product in which test of content of sodium and loss on drying is included. Further claimed that they follow USP specification for drug product.	
18.	As per the submitted master formulation 1000mg per vial quantity has been filled while the weight variation limit specified is 1.445gm±3% per vial justification is required regarding the disparity in filled weight of active material.	Firm submitted the revised master formulation along with calculation of filled weight.	
19.	• As per the submitted procedure of assay, sample solution has been prepared in mobile phase in which 50mg of meropenem has been dissolved initially while according to the USP "*Constitute a container of Meropenem for Injection with a volume of water corresponding to the quantity of solvent specified in the labeling, and dilute with water".* Justify how your method could be considered as complying with USP monograph. • The USP monograph under the assay method specifies that sample should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph. • Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer.	Firm submitted the revised analytical procedure in compliance of USP monograph of Meropenem Injection.	

	• Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.		
20.	• Submit data of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer. • Provide the data of verification studies along with the raw data sheet reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.	Submitted	
21.	Scientific justification for not performing the test of sodium content and loss on drying for the analysis of all three batches of drug product.	Firm submitted the batch analysis report	
22.	As per the batch analysis certificate manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while the section approval was granted on 14th October, 2020.Clarification is required regarding the manufacturing of batches prior section approval, further specify where the manufacturing of these batches was carried out.	Firm did not clarify the manufacturing dates of trial batches , since, initially the manufacturing date of trial batches of both 500mg and 1000mg was the year 2019, later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.	
23.	Provide COA of primary / secondary reference standard including source and lot number.	submitted	
24.	Stability Following clarification is required regarding the date of manufacturing of batches for product development and stability studies: • As per the batch analysis certificate, manufacturing date of Batches MP01, MP02, MP03 are 03-2019,04-2019 and 05-2019 respectively while as per stability data sheets same batches has been manufactured on MP01: 03-2021, MP02:04-2021, MP03:05-2021.Clarification is required in this regard.	Firm clarified that the trial batches of 500mg is ME-01,ME-02,ME-03,while the trial batches of 1000mg is MP-01,MP-02,MP-03.	
25.	Justify why the test of content of sodium and loss on drying has not been performed during the stability studies of drug product.	Firm submitted the revised stability data in which both of these tests are included.	
26.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Not submitted	
27.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Submitted	
28.	Provide Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted	

29.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted	
30.	• Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted	
31.	Executed Production Documents Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted	

Decision of 331st meeting of Registration Board:
Deferred for submission of following shortcomings:

- Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.
- Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Response of the Firm:

- Submit stability study data of three batches of the drug substance as per the zone IV-a conditions.

Firm submitted the stability data of three batches of the drug substance as per the zone IV-a conditions.

- Clarification regarding the manufacturing dates of trial batches, since initially year 2019 was mentioned on batch analysis certificates of all three trial batches later firm submitted the revised stability data in which date of manufacturing of three trial batches were 03-2021.

Firm replied that in 2019 their carbapenem section was ready for inspection but the inspection process of our section was under process and during this period we got the raw material on loan basis and processed our trial batches. Later, they were told that it will not be approved because they don't have a section approval letter and proof of import is also required, so they stopped the work on previous trial batches and initiated new studies after the section approval. After section approval we imported the raw material from Shenzhen Haibin Pharmaceuticals China, via DHL.
Further firm claimed that the old stability documents were withdrawn and previous working was nullified so they used the same batch number MP01, MP02, MP03 for 1000mg of their new trial batches.

- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Firm replied that the Batch no. 8MT2102165 is used in all three batches of finished product stability, which was imported from China via DHL and DHL invoice has been submitted by the Firm.

The invoices submitted by the firm were not verifiable.

Decision: Deferred for evidence of procurement/import of drug substance with approval of DRAP I&E Office, since the submitted DHL courier receipt is not verifiable.

450.	Name, address of Applicant / Marketing Authorization Holder	M/s Wahabsons pharmaceuticals (Pvt) Ltd, 4 km Bunner Road, Barikot,Swat
	Name, address of Manufacturing site.	M/s Wahabsons pharmaceuticals (Pvt) Ltd, 4 km Bunner Road, Barikot,Swat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Renewal of DML with the regularization of following sections dated 29th April,2022: Capsule Section, Oral Liquid Section. Licensing status needs to be confirmed from the Licensing Division.
	Evidence of approval of manufacturing facility	Not confirmed
	Status of application	☒ Generic Drug Product (GDP) ☐ New Drug Product (NDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.no. 13179 dated 29-05-2023
	Details of fee submitted	PKR 30,000/- Dated 23-05-2023
	The proposed proprietary name / brand name	OMI 20mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole……20mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Pharmaceutical form of applied drug	Capsules
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 20mg Capsule of M/s Sandoz Ltd UK (USFDA approved)
	For generic drugs (me-too status)	Risek 20 mg Capsule of M/s GETZ Pharma (Reg # 019364)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time

		stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence and CDP of test formulation with comparator product Losec 20 mg Capsule (B # YEVA, Mfg Date: 09-2021, Exp Date 08-2024) of M/s Astrazeneca (Manufactured by M/s. Astrazeneca and Imported by M/s. Barrett & Hodgson, Pakistan. The results of the tests of both products were found to be within the specifications and are comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	OMP1158		
Description of Pack (Container closure system)	14's blisters packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tr-001	Tr-001	Tr-001
Batch Size	2000 caps	2000 caps	2000 caps
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	15-08-2022	15-08-2022	15-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Vision pharma pvt Ltd, Lahore issued by DRAP Lahore. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of omeprazole EC pellets from M/s vision pharma dated 14-07-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.1 - 3.2.S.4.2	• Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".	Firm submit the specification and analytical of drug substance by drug product manufacturer only. Specification and Analytical Procedure of drug substance by drug substance manufacturer is not submitted by the firm.
2.	3.2.S.4.2	Further, justify the performance of dissolution testing on UV spectrophotometer by the drug substance manufacturer since the USP recommends test of dissolution on HPLC.	Firm replied that the drug substance manufacturer uses UV method for analysis of drug substance but they use HPLC method for both drug substance and drug product.
3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm submitted the analytical method verification report in which the target concentration 0.3 mg/ml instead of 0.2mg/ml as per the submitted analytical procedure.
4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance*	Firm submitted the Batch analysis report of drug substance.

			performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drugsubstance / API by Drug Product manufacturer (e.g.results not tested according to the proposed specification)".		
	5.	3.2.P.2.2 .1	• Calculations of comparative dissolution profile is not in accordance with guidelines approved in 293rd meeting of Registration Board with reference to following points: • For f2 calculations a minimum of three time points (excluding point zero) must be used; mentioned the time point which were considered for the calculation of f2 value.	Firm replied that 3 time points were used during Comparative dissolution profile for buffer media at pH 6.8, the reading of 3rd time point are more than 85%, therefore no further reading required.	
	6.		Provide complete calculations of f2 value in all three physiological mediums.	Firm did not submit the reply of this query. Later Firm submit the F2 value calculations in all three physiological mediums.	
	7.	3.2.P.2.2 .1	Submit data of Pharmaceutical equivalenceof the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm did not submit the reply of this query.	
	8.	3.2.P.5.3	Justify for performing the verification studies of assay procedure different from the method recommended in USP monograph of "Omeprazole delayed release capsule". Analytical method of drug product specifies that concentration of standard and sample preparation is 0.2mg/ml while you have performed verification studies	Firm replied that the Higher conc. Was taken to minimize errors in readings and graphs and for better resolution.	

			keeping the target concentration 0.4mg/ml. Justify how these studies represent your analytical method which is in complies with USP monograph.		
	9.	3.2.P.8	• Justify for keeping the run time around 4.5-5mins as evident from the submitted chromatogram, since the USP monograph recommends HPLC system of gradient elution over run time of 25minutes. • Justify how can the retention time, peak area, peak height, area% as well as height % of sample solutions on all the provided chromatograms of both strengths were same upto three digits.	Firm replied that we perform tests and present the data as we received during the test and analysis and respectively calculate the values according to received data.	
	10.	3.2.P.8	• Submit raw data sheets and chromatograms of dissolution test since you have only submitted the chromatograms of assay. • Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm replied that our HPLC Logs are recorded manually and we can share pages of our log book for your consideration.	

Decision of 330th meeting of Registration Board:
Deferred for submission of following:

- Specification and analytical procedure of drug substance by drug substance manufacturer.
- Analytical verification report of drug substance performed in accordance with analytical procedure given in section 3.2. S.4.2.
- Data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests should be submitted.
- Analytical Verification report of drug product performed in accordance with USP monograph of "Omeprazole Capsule".
- Justification for keeping the run time around 4.5-5mins as evident from the submitted chromatogram, while the USP monograph recommends HPLC system of gradient elution over run time of 25minutes.
- Justify how can the retention time, peak area, peak height, area% as well as height % of sample solutions on all the provided chromatograms of both strengths were same upto three digits.

Response of the Firm:

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Specification and analytical procedure of drug substance by drug substance manufacturer.	Firm submitted the specification and analytical procedure of drug substance
2.	Analytical verification report of drug substance performed in accordance with analytical procedure given in section 3.2. S.4.2.	Firm submitted the analytical verification report of drug substance by keeping the target concentration of sample solution 0.3mg/ml, while assay method given in section 3.2.S.4.2 specified that the final concentration of sample solution should be 0.2mg/ml.

	3.	Data of Pharmaceutical equivalence ofthe applied drug with the innovator / reference/ comparator product and results of all the quality tests should be submitted.	Firm submitted the Pharmaceutical equivalence report of esomeprazole capsule instead of omeprazole capsule.	
	4.	Analytical Verification report of drug product performed in accordance with USP monograph of "Omeprazole Capsule".	Firm submitted the analytical verification report of drug product which is not in accordance with USP monograph of "Omeprazole Capsule".	
	5.	Justification for keeping the run time around 4.5-5mins as evident from the submitted chromatogram, while the USP monograph recommends HPLC system of gradient elution over run time of 25minutes.	Firm has submitted chromatograms as per USP monograph	
	6.	Justify how can the retention time, peak area, peak height, area% as well as height % of sample solutions on all the provided chromatograms of both strengths were same up to three digits.		

Decision: Deferred for submission of following shortcomings:

- **Confirmation of validity of Drug Manufacturing License from Licensing Division.**
- **Analytical method verification report of drug substance performed in accordance with analytical procedure given in section 3.2.S.4.2.**
- **Data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests should be submitted.**
- **Analytical method Verification report of drug product performed in accordance with USP monograph of "Omeprazole Capsule".**

451.	Name, address of Applicant / Marketing Authorization Holder	M/s Wahabsons pharmaceuticals (Pvt) Ltd, 4 km Bunner Road, Barikot,Swat
	Name, address of Manufacturing site.	M/s Wahabsons pharmaceuticals (Pvt) Ltd, 4 km Bunner Road, Barikot,Swat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Renewal of DML with the regularization of following sections dated 29th April,2022: Capsule Section, Oral Liquid Section. Licensing status needs to be confirmed from the Licensing Division.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of Renewal of DML with the following sections dated 29th April, 2022 specifying Capsule Section, Oral Liquid Section.
	Status of application	☒ Generic Drug Product (GDP) ☐ New Drug Product (NDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.no. 13180 dated 29-05-2023
	Details of fee submitted	PKR 30,000/- Dated 23-05-2023
	The proposed proprietary name / brand name	OMI 40mg Capsules

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole……40mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Pharmaceutical form of applied drug	Capsules
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg Capsule of M/s Sandoz Ltd UK (USFDA approved)
	For generic drugs (me-too status)	Risek 40 mg Capsule of M/s GETZ Pharma (Reg # 022109)
	Name and address of API manufacturer.	M/s Vision pharmaceuticals (pvt) Ltd., Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence and CDP of test formulation with comparator product Risek 40 mg Capsule (B# 004067, Mfg Date: 04-2022, Exp Date 04-2025) of M/s. Getz Pharma,Karachi. The results of the tests of both products were found to be within the specifications and are comparable.

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

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	OMP1158		
Description of Pack (Container closure system)	14's blisters packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tr-004	Tr-005	Tr-006
Batch Size	2000 caps	2000 caps	2000 caps
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	17-08-2022	17-08-2022	17-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Vision pharma pvt Ltd, Lahore issued by DRAP Lahore. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of omeprazole EC pellets from M/s vision pharma dated 14-07-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.1 - 3.2.S.4.2	• Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical	Firm submit the specification and analytical of drug substance by drug product manufacturer only. Specification and Analytical Procedure of drug substance by drug substance manufacturer is not submitted by the firm.

			procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".		
	2.	3.2.S.4.2	Further, justify the performance of dissolution testing on UV spectrophotometer by the drug substance manufacturer since the USP recommends test of dissolution on HPLC.	Firm replied that the drug substance manufacturer uses UV method for analysis of drug substance but they use HPLC method for both drug substance and drug product.	
	3.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturerfor both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm submitted the analytical method verification report in which the target concentration 0.3 mg/ml instead of 0.2mg/ml as per the submitted analytical procedure.	
	4.	3.2.S.4.3	Submit batch analysis report of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".*	Firm submitted the Batch analysis report of drug substance.	
	5.	3.2.P.2.2 .1	• Calculations of comparative dissolution profile is not in accordance with guidelines approved in 293rd meetingof Registration Board with	Firm replied that 3 time points were used during Comparative dissolution profile for buffer media at pH 6.8, the reading of 3rd time point are more than 85%, therefore no further reading required.	

			reference to following points: • For f2 calculations a minimum of three time points (excluding point zero) must be used; mentioned the time point which were considered for the calculation of f2 value.		
	6.		Provide complete calculations of f2 value in all three physiological mediums.	Firm did not submit the reply of this query	
	7.	3.2.P.2.2.1	Submit data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm did not submit the reply of this query.	
	8.	3.2.P.5.3	Justify for performing the verification studies of assay procedure different from the method recommended in USP monograph of "Omeprazole delayed release capsule". Analytical method of drug product specifies that concentration of standard and sample preparation is 0.2mg/ml while you have performed verification studies keeping the target concentration 0.4mg/ml. Justify how these studies represent your analytical method which is in complies with USP monograph.	Firm replied that the Higher conc. Was taken to minimize errors in readings and graphs and for better resolution.	
	9.	3.2.P.8	• Justify for keeping the run time around 4.5-5mins as evident from the submitted chromatogram, since the USP monograph recommends HPLC system of gradient elution over run time of 25minutes. • Justify how can the retention time, peak area, peak height, area% as well as height % of sample solutions on all the provided chromatograms of both strengths were same upto three digits.	Firm replied that we perform tests and present the data as we received during the test and analysis and respectively calculate the values according to received data.	

	10.	3.2.P.8	• Submit raw data sheets and chromatograms of dissolution test since you have only submitted the chromatograms of assay. • Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm replied that our HPLC Logs are recorded manually and we can share pages of our log book for your consideration.	

Decision of 331st meeting of Registration Board:

Deferred for submission of following:

- Specification and analytical procedure of drug substance by drug substance manufacturer.
- Analytical verification report of drug substance performed in accordance with analytical procedure given in section 3.2.S.4.2.
- Data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests should be submitted.
- Analytical Verification report of drug product performed in accordance with USP monograph of "Omeprazole Capsule".
- Justification for keeping the run time around 4.5-5mins as evident from the submitted chromatogram, while the USP monograph recommends HPLC system of gradient elution over run time of 25minutes.
- Justify how can the retention time, peak area, peak height, area% as well as height % of sample solutions on all the provided chromatograms of both strengths were same upto three digits.

Response of the Firm:

Sr.no.	Decision of Registration Board	Response of the Firm
1.	Specification and analytical procedure of drug substance by drug substance manufacturer.	Firm submitted the specification and analytical procedure of drug substance
2.	Analytical verification report of drug substance performed in accordance with analytical procedure given in section 3.2. S.4.2.	Firm submitted the analytical verification report of drug substance by keeping the target concentration of sample solution 0.3mg/ml, while assay method given in section 3.2.S.4.2 specified that the final concentration of sample solution should be 0.2mg/ml.
3.	Data of Pharmaceutical equivalence ofthe applied drug with the innovator / reference/ comparator product and results of all the quality tests should be submitted.	Firm submitted the Pharmaceutical equivalence report of esomeprazole capsule instead of omeprazole capsule.
4.	Analytical Verification report of drug product performed in accordance with USP monograph of "Omeprazole Capsule".	Firm submitted the analytical verification report of drug product which is not in accordance with USP monograph of "Omeprazole Capsule".
5.	Justification for keeping the run time around 4.5-5mins as evident from the submitted chromatogram, while the USP monograph recommends HPLC system of gradient elution over run time of 25minutes.	Firm has submitted chromatograms as per USP monograph
6.	Justify how can the retention time, peak area, peak height, area% as well as height % of sample solutions on all the provided chromatograms of both strengths were same up to three digits.	

Decision: Deferred for submission of following shortcomings:

- **Confirmation of validity of Drug Manufacturing License from Licensing Division.**

- **Analytical method verification report of drug substance performed in accordance with analytical procedure given in section 3.2.S.4.2.**
- **Data of Pharmaceutical equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests should be submitted.**
- **Analytical method Verification report of drug product performed in accordance with USP monograph of "Omeprazole Capsule".**

Cases of Form 5-D:

452.	Name and address of manufacturer / Applicant	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Brand Name +Dosage Form + Strength	Nebilol-V Tablet 5mg+80mg
	Composition	Each Film coated tablet contains: Nebivolol hydrochloride eq. to Nebivolol….5mg Valsartan …… 80mg
	Diary No. Date of R& I & fee	Dy. No.3314 dated 19-05-2017 Fee Rs: 50,000/- dated 19-05-2017 vide deposit slip No.0515343 .0.Stability data submitted on 19-02-2021
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's & 30's As per PRC
	Approval status of product in Reference Regulator Authorities	Vyduo Tablet 5mg+80mg Prinston Pharmaceuticals Inc. Ltd
	Me-too status	Not Available
	GMP status	New GMP granted on 13/06/2023 Tablet Section
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	Nebivolol HCl: Cadila Pharmaceutical Ltd. Valsartan: Zhejiang Tianyu Pharmaceutical ltd.		
API Lot No.	Nebivolol HCl: 19NV003 Valsartan: 10250-190402		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 3 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	19SB-168-01	19SB-169-02	19SB-170-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	19-09-2019	19-09-2019	19-09-2019

<table>
<tr><td colspan="2">No. of Batches</td><td>03</td></tr>
<tr><td colspan="2">Date of Submission</td><td>19-02-2021</td></tr>
<tr><td colspan="3">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>Sr. No.</td><td>Documents to Be Provided</td><td>Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Not applicable</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Nebivolol HCl:
Stability study conditions:
Real time: 30°C ± 3°C / 65% ± 5%RH for 60 months
Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
Batches: 0NL032, 0NL033, 0NL034
Valsartan:
Stability study conditions:
Real time: 30°C ± 3°C / 65% ± 5%RH for 60 months
Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
Batches: 201207301, 201207302, 201207303</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Nebivolol HCl:
Copy of GMP certificate valid till 18-10-2021
Valsartan:
Copy of GMP certificate valid till 28-03-2022</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Purchase invoice No. Nebivolol HCl 3201940106 Cleared from ADC dated 01-03-2019 are submitted.
Copy of Purchase invoice No. Valsartan TYI19306 Cleared from ADC dated 14-06-2019 are submitted.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Drug excipients compatibility study performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>19SB-168-01</td><td>1500 Tablets</td><td>08-2019</td></tr>
<tr><td>19SB-169-02</td><td>1500 Tablets</td><td>08-2019</td></tr>
<tr><td>19SB-170-03</td><td>1500 Tablets</td><td>08-2019</td></tr>
</table></td></tr>
</table>

11.	Record of comparative dissolution data (where applicable)	CDP has been performed against the brand that is Byvalson Tablet 5mg/80mg (B#w00551) Forest Research Institute, in Acid media (0.1N HCl), acetate buffer 4.5 & Phosphate Buffer pH (6.8). The f2 value was in acceptable range.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

Sr.no.	Shortcomings/Observations	Response of the Firm
1.	Submit analytical method used for analysis of APIs from both API Manufacturer and Finished Product Manufacturer	Firm submitted the analytical method used for analysis of APIs from both API Manufacturer and Finished Product Manufacturer.
2.	Submit certificate of analysis of APIs from both API Manufacturer and Finished Product manufacturer.	Submitted the COAs of both API.
3.	Provide approval of API/ DML/GMP certificate of both API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the certificate of both API manufacturer.
4.	Submit documents for the procurement of both API with approval from DRAP (in case of import).	Firm submitted the DRAP attested invoice for the procurement of both API.
5.	Submit analytical method used for analysis of finished pharmaceutical product.	Firm submit the analytical method used for analysis of finished pharmaceutical product.
6.	Provide record of comparative dissolution data.	Firm submit the CDP report of finished product.
7.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Decision: Approved with Innovator's specifications.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

453.	Deferred case:	
	Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals Pvt., Ltd. 44-Industrial Triangle Kahuta Road Islamabad Pakistan
	Name, address of Manufacturing site.	M/s M/s Focus & Rulz Pharmaceuticals Pvt., Ltd. 44-Indutrial Triangle Kahuta Road Islamabad Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.5220 dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: dated 20-05-2022
	The proposed proprietary name / brand name	Delergic Syrup

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Desloratadine USP…… 0.5mg (Innovator Specifications)
	Pharmaceutical form of applied drug	Colorless, clear solution, without agglomerate, foreign particles.
	Pharmacotherapeutic Group of (API)	Anti-histamine, Anti-allergic
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarinex (Desloratadine) Syrup Company: Schering Corporation USFDA Approved
	For generic drugs (me-too status)	Jardin-D Syrup 0.5mg/ml by M/s High-Q Pharmaceuticals (Reg.no. 073610).
	GMP status of the Finished product manufacturer	DML No 00628 granted on 19/06/2018 (Syrup section is approved).
	Name and address of API manufacturer.	M/s Glenmark Life Sciences Limited, Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakari Audyogik Vasahat, Maryadit, Pune-Hyderabad Highway Mohol – 413213, Dist. Solapur, Maharashtra State, India..
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Desloratadine is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for Desloratadine,(fluoro Desloratadine, Desloratadine related compound B, & unspecified impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (84160288, 84160291, 84160300)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Not submitted

	Analytical method validation of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Glenmark Life Sciences Limited, Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakari Audyogik Vasahat, Maryadit, Pune-Hyderabad Highway Mohol – 413213, Dist. Solapur, Maharashtra State, India		
API Lot No.		84200308		
Description of Pack (Container closure system)		120ml Amber colored glass bottle.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		21CT04	21CT05	21CT06
Batch Size		200 Bottles	200 Bottles	200 Bottles
Manufacturing Date		03-2021	03-2021	03-2021
Date of Initiation		09-04-2021	09-04-2021	09-04-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. MH/102854 issued by CFDA valid till 31/12/2023 submitted.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of ADC approved invoice No.F30000001207, dated 03-12-2020 for 2.0 Kg Desloratadine imported from Glenmark Life Sciences Limited, cleared from DRAP office dated 18-12-2020 submitted.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Stability studies data, supported with Chromatograms and raw data sheets for three batches i.e. 21CT04, 21CT05 and 21CT06 is submitted.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software is 21CFR complaint & complete audit trail reports on product testing is submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers is submitted		

Remarks OF Evaluator:

S.no.	Observations/Deficiencies/ Short-comings
1.	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.
2.	Provide COA of drug substance by drug substance manufacturer.

3.	Submit COA of reference/working standard which was used by drug product manufacturer for analysis of API.	
4.	Formulation contain preservative sodium benzoate, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	
5.	Justify the use of saccharin in the syrup formulation, since the review document of reference product approve in EMA clearly mentioned that *saccharin was not found acceptable from peadriatic point of view.*	
6.	Submit data of Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed	
7.	Submit the analysis report/COA of excipients propylene glycol, sorbitol and glycerine, which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide No. F.6-30/2022-QA dated 21-10-2022.	
8.	According to the review literature of reference product approved in Ema stability of active substance is demonstrated to be optimal in a solution with a pH between 5 and 6, Justify for keeping the pH acceptance limit between 4-5.5 when the stability of drug substance is optimized in the solution with a pH between 5 and 6.	
9.	Justify for not including the test of extractable volume and microbial content test in the finished product specification , since these tests are recommended by the pharmacopeia in their general chapter for oral solution preparation.	
10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.	Submitted
2.	Provide COA of drug substance by drug substance manufacturer.	Submitted
3.	Submit COA of reference/working standard which was used by drug product manufacturer for analysis of API.	Submitted
4.	Formulation contain preservative sodium benzoate, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted the preservative efficacy report of sodium benzoate instead of drug product containing sodium benzoate as recommended in pharmacopeia.
5.	Justify the use of saccharin in the syrup formulation, since the review document of reference product approve in EMA clearly mentioned that *saccharin was not found acceptable from peadriatic point of view.*	Firm replied that "Saccharin is not used in trial batches as evidence in master formulation and MOA in the submitted BMRs with stability studies. It is a typographical error in the formulation provided in 3.2.P.1 of the dossier and we apologize for that mistake. Revised 3.2.P.1 is enclosed for your kind consideration.
6.	Submit data of Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference/ comparator product	Firm submitted Pharmaceutical Equivalence report against the comparator product Jardin –D 0.5mg/ml

		and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed	Syrup of M/s. High-Q Pharmaceuticals Korangi Industrial Area Karachi.	
	7.	Submit the analysis report/COA of excipients propylene glycol, sorbitol and glycerine, which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide No. F.6-30/2022-QA dated 21-10-2022.	Firm submitted the certificate of test or analysis on Form-6 for propylene glycol and sorbitol.	
	8.	According to the review literature of reference product approved in Ema stability of active substance is demonstrated to be optimal in a solution with a pH between 5 and 6, Justify for keeping the pH acceptance limit between 4-5.5 when the stability of drug substance is optimized in the solution with a pH between 5 and 6.	Firm replied that the result of both product (test and reference) are within acceptable limits of innovator Product as evident from the submitted pharmaceutical equivalence report. Further firm claimed that pH of their product is stable during stability studies of product (but the pH adjusted for all trial batches were below 5 as evidentfrom the submitted BMR). To comply with the specification of innovator product, the specification of the product are revised as per innovator product to implement on commercial batches.	
	9.	Justify for not including the test of extractable volume and microbial content test in the finished product specification , since these tests are recommended by the pharmacopeia in their general chapter for oral solution preparation.	Firm replied that the test of extractable volume and microbial test are included in the finished product specification and revised finished product specification is submitted.	
	10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Submitted	

Decision of 331st meeting of Registration Board:
Deferred for submission of following:

- Preservative effectiveness studies performed in accordance with USP general chapter <51> Antimicrobial Effectiveness testing.
- Justification for adjusting the final pH of oral solution below value 5 as evident from the submitted of Batch Manufacturing Record (BMR) of trial batches.

Response of the Firm:

- Preservative effectiveness studies performed in accordance with USP general chapter <51> Antimicrobial Effectiveness testing.

Firm submitted the preservative efficacy test performed on drug product in accordance with USP general chapter <51> Antimicrobial Effectiveness testing.

- Justification for adjusting the final pH of oral solution below value 5 as evident from the submitted of Batch Manufacturing Record (BMR) of trial batches.

Firm replied that initially the innovator's pH specification was not available and they have no idea of the pH range of the innovator product. They prepared and set the pH of the trial batches according to research data that falls near to the innovator's pH range. Further, for commercial batches, firm commit that they will shift to innovator's specification to comply the innovator's specification as a reference i.e. pH range 5.0-6.0.

Decision: Approved.

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

Registration Application Withdrawal Request by M/s. Citi Pharma Pvt. Ltd., Kasur:

M/s. Citi Pharma Pvt. Ltd. requested for withdrawal of registration application of following products vide letter no. CP/FOM/2023/019 dated 11-12-2023, which were defer in 330th meeting of Registration Board for *verification of DRAP attested documents related to the procurement of API*. In their letter firm stated that "we citi Pharma Pvt. Ltd. writing to inform you about a situation regarding the misalignment of documents related to a product that was submitted to DRAP Pakistan. Due to this issue, I would like to formally request the withdrawal of the product from the system.
The detail of the products are as follows:

1. Cef-slub 1g Injection (sterile powder Cefoperazone Sodium JP eq. to Cefoperazone …500mg +Sulbactam Sodium eq. to Sulbactam….500mg)
2. Cef-slub 2g Injection (sterile powder Cefoperazone Sodium JP eq. to Cefoperazone …1g +Sulbactam Sodium eq. to Sulbactam….1g)

Detail of the case of above-mentioned products presented in 330th meeting of Registration Board is as under:

454.	**Name, / Marketing Authorization Holder address of Applicant**	**M/s Citi Pharma Private Limited**
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9107 dated 11-04-2022
	Details of fee submitted	Rs.30,000/- dated 28-03-2022
	The proposed proprietary name / brand name	Cef-Sulb Injection 1gm
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder Cefoperazone sodium MS equivalent to Cefoperazone…..... 500mg Sterile Powder Sulbactam sodium MS equivalent to Sulbactam 500mg
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Sulperazone Injection 1gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 1gm by Global Pharmaceuticals, Reg. No. 042552
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefoperazone sodium /Sulbactam sodium eq to Cefoperazone /Sulbactam not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (T-CSP001, T-CSP002, T-CSP003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Toxirid Injection 1gm by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China		
API Lot No.	CEFP17/023/06/21		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-CSP001	T-CSP001	T-CSP001

Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	26-09-2021	26-09-2021	26-09-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20191025 issued by CFDA valid till 10/12/2024.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Letter No. 11160/2021/DRAP Dated: 27-07-2021 B/L No. 176-6445-291 dated: 31-07-2021	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	

Remarks OF Evaluator:

Deficiencies/ Short-comings

Shortcomings communicated to the Firm:

- You have mentioned USP specification in section 1.5.6 in module 1, while the drug product monograph is not available in USP, but present in JP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both USP and in-house standards for the drug substance, provide scientific justification in this regard.
- Justify, how you have claimed USP specification for drug substance cefoperazone sodium+Sulbactum30-May-22 sodium, when the monograph has not been present in USP.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance manufacturers."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Stability study data of 3 batches of drug substances till the assigned shelf life needs to be submitted, since stability data of 3 months has submitted despite the batch had been manufactured in 2017.
- Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".
- Justify the use of 4ml printed glass vial for packaging of drug product with reference to the volume of diluent used for reconstitution of dry powder for injection as per innovator product.
- Justify how you have performed pharmaceutical equivalence studies using the reference product of different strength.

- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting of Registration Board, which states that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".
- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"
- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Justify the weight variation limit of filled vial from1107-1152mg with reference to the claimed potency of both actives.
- Provide the Pharmacopeial reference of finished product specifications, since USP specs are mentioned in module 1, and USP does not contain any monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection. However, monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopeia.
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the document submitted in section 3.2.P.8 batch no. T-CSP-002 and T-CSP-003 has been manufactured on 02-2021, while stability study data sheet submitted in section 3.2.P.8.3 stated these batches were manufactured in sep-2021. Clarification required in this regard.
- Specify the batch size of all three stability batches.
- Justify the pH acceptance criteria (6.0-8.0) and water content acceptance limit (8.0-11%) set for drug product with the acceptance criteria mentioned on COA of drug substance by drug substance manufacturer i.e. 4.5-6.5 and NMT 3.0%. Elevation of pH and water content of drug product without any further processing of formulation needs to be justify with the pharmacopeial reference and innovator product.
- Assay content of both active should be separately calculated and mentioned as per pharmacopeial reference and innovator product.
- As per release specification of drug product acceptance criteria of assay is 90-110% while the stability data sheet represents that assay content should be between 90-115%. Justification is required regarding the variation in acceptance limit of assay content in various section of module-III.
- Justify why the sterility test is not included in the stability studies of the product.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
- In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.

Remarks of the Evaluator:
In response of above shortcomings, firm has submitted a complete new CTD dossier with fee of Rs.7500/- in which drug substance was imported from a new source and accordingly data of trial batches of drug product manufactured from new source of drug substance has submitted. Newly submitted dossier has again evaluated and presented below before the Board for its consideration.

455.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22143 dated 11/04/2022
	Details of fee submitted	PKR 7,500/-: dated 02/08/2022
	The proposed proprietary name / brand name	Cef-Sulb Injection IV/IM 1gm
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder Cefoperazone sodium JP equivalent to Cefoperazone…….500mg Sterile Powder Sulbactam sodium JP equivalent to Sulbactam…….500mg
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 1gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 1gm by Global Pharmaceuticals, Reg. No. 042552
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co. Ltd. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefoperazone sodium /sulbactam sodium Injection is present in JP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (2003FJ81NH, 2002FJ81NH, 2001FJ81NH)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product 2SUM (Cefoperazone Sodium + Sulbactam Sodium) 1g Injection of M/s. Healthtek Pvt. Ltd. Karachi, performing quality tests (Identification, Assay, constituted solution, BET & sterility test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Qilu Antibiotic Pharmaceutical Co. Ltd. China		
API Lot No.	2001FJ81NH		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRI003-01	TRI003-01	TRI003-01
Batch Size	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	26-01-2022	26-01-2022	26-01-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Qilu Antibiotics Pharmaceuticals Co. Ltd., China vide Dy. No. 11160/2021 DRAP Dated: 27-12-2021. Invoice attested vide Dy.no. 11160/2021 DRAP dated: 27-12-2021in which shipper was M/s. Shandong Luoxin Pharmaceuticals, China.

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

Remarks OF Evaluator:

Sr.no.	Section	Shortcomings/Observations
1.	3.2. S.4.1	Acceptance criteria of assay mentioned in specification of drug was not in accordance with JP monograph. Assay limit mentioned in COA and specification of drug substance by both drug substance manufacturer "JP drug product manufacturer was than on anhydrous basis cefoperazone ≥43.5% and sulbactam on anhydrous basis ≥44.5%. Assay acceptance criteria in accordance with monograph is It contains not less than 90.0% and not more and 110.0% of the labeled potency of Cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24)".
2.	3.2. S.4.3	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2. S.5	Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
4.	3.2. S.7	Firm has submitted only 6 months long term stability data of all three batches of drug substance.
5.	3.2P.2.1(a)(b)	Firm has not provided any details related to weight of powder filled per vial keeping in view the sodium content of both active substances.
6.	3.2.P.2.1(C)	Firm has not provided any details regarding the type of diluent, its composition, quantity or volume, specifications (as applicable) in which drug product has to be reconstitute before administration.
7.	3.2. P.2.2.1	Firm has submitted the pharmaceutical equivalence report in which the acceptance criteria of all the quality test was not in accordance with JP monograph: Acceptance criteria in pharmaceutical equivalence report / Acceptance criteria in JP monograph pH (6.0-8.8) / pH (4.5-6.5) Assay (90%-110%) / Assay (It contains not less than 90.0 and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24).) Bacterial Endotoxin Test (NMT 0.2 USP Endotoxin unit per mg) / Bacterial Endotoxin Test (Less than 0.060 EU/mg (potency).) Further firm has not performed water content test and clarity and color of solution test which are also included in JP monograph.
8.	3.2. P.5.2	Firm has not submitted the analytical procedure used for testing of drug product.
9.	3.2.P.5.3	Analytical method verification report reflects that the assay has performed on UV method while the JP monograph recommends the HPLC method for assay of drug product.
10.	3.2.P.6	Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.
11.	3.2.P.8	Firm has not submitted following documents to support the stability data of drug product: • Reference of previous approval of applications with stability study data of the firm (if any)

		• Documents for the procurement of API with approval from DRAP (in case of import). • Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin. • Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.	
12.	3.2.R	Firm has not submitted the copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	

Decision of 321st meeting of Registration Board:

- Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.
- Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
- Submit long term stability data of drug substance till the claimed shelf life.
- Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.
- Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.
- Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.
- Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug product.
- Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.
- Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Reply of the Firm:

Sr.no.	Decision	Response of the Firm
1.	Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.	Firm replied that "Ask the supplier about analytical method verification ,will be dispatched soon".
2.	Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.	Firm replied that "By mistake it was attached, actual criteria of drug substance as per JP monograph".

3.	COA of primary / secondary reference standard including source and lot number used for testing of drug substance.	Firm submitted the COA of USP primary reference standard
4.	Submit long term stability data of drug substance till the claimed shelf life.	Firm replied that " Ask to supplier for long term stability, will be dispatched soon."
5.	Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.	Firm submitted the formulation table in which only the material has been listed with the information that the API (cefoperazone sodium plus sulbactum sodium) was used 3% in excess, while the calculation of dispense quantity of API per vial was not submitted by the firm.
6.	Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.	Firm submitted the pharmaceutical equivalence report in which all the quality test has been performed.
7.	Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.	Submitted
8.	Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.	Submitted
9.	COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted
10.	Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.
11.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Not submitted
12.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Not submitted
13.	Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm submitted the fee of Rs.30,000/- vide slip no. 057382167110 dated 04-11-2022

Decision of 323rd meeting of Registration Board:
Deferred for submission of following:

- Submit analytical method verification studies including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.
- COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
- Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.
- Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Response of the Firm:
Submit analytical method verification studies including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.

Firm submit the analytical verification report including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F. COA of primary / secondary reference standard including source and lot number used for testing of drug substance. Firm submit the copy of COA of primary reference standard of USP of both active substances, while the claimed specification of premixed powder of both API is JP specification. Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1. In their reply firm only submitted the composition table mentioning the quantity of both active per vial i.e. Cefoperazone sodium+ Sulbactam sodium 2gm per vial, instead of giving complete calculation of weight of powder filled per vial keeping in view the sodium content of both active substances. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin. Firm submit the valid GMP certificate of the Drug Substance manufacturer, which is valid till 13-12-2023. Previously firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. Now the firm again submitted a new invoice, in which the Beneficiary is Qilu Pharmaceuticals Co. Ltd, China while the Manufacturer is M/s. The United Laboratories (Inner Mongolia), China quantity of 10kg is imported dated 21-06-2021, attested by DRAP vide dy.no.11160/2021 DRAP dated 27-12-2021. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.		
Decision of 330th meeting of Registration Board: Deferred for verification of DRAP attested documents related to the procurement of API.		
456.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Dru g Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9108 dated 11-04-2022
	Details of fee submitted	PKR 30,000/-: dated 28/03/2022
	The proposed proprietary name / brand name	Cef-Slub Injection 2gm IV/IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefoperazone sodium MS equivalent to Cefoperazone 1g Sterile Powder of Sulbactam sodium MS equivalent to Sulbactam 1g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic

	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 2gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 2gm by Global Pharmaceuticals, Reg. No. 042555
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefoperazone sodium /Sulbactam sodium eq to Cefoperazone /Sulbactam is present not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (T-CSP001, T-CSP002, T-CSP003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Toxirid Injection 2gm by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China
API Lot No.	CEFP17/023/06/21
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

		Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-CSP001	T-CSP001	T-CSP001
Batch Size		1000 Vials	1000 Vials	1000 Vials
Manufacturing Date		09-2021	09-2021	09-2021
Date of Initiation		26-09-2021	26-09-2021	26-09-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20191025 issued by CFDA valid till 10/12/2024.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Letter No. 11160/2021/DRAP Dated: 27-07-2021 B/L No. 176-6445-291 dated: 31-07-2021		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks OF Evaluator:

Deficiencies/ Short-comings

Shortcomings communicated to the Firm:

- You have mentioned USP specification in section 1.5.6 in module 1, while the drug product monograph is not available in USP, but present in JP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both USP and in-house standards for the drug substance, provide scientific justification in this regard.
- Justify, how you have claimed USP specification for drug substance cefoperazone sodium+Sulbactum30-May-22 sodium, when the monograph has not been present in USP.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance manufacturers."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Stability study data of 3 batches of drug substances till the assigned shelf life needs to be submitted, since stability data of 3 months has submitted despite the batch had been manufactured in 2017.

- Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".
- Justify the use of 4ml printed glass vial for packaging of drug product with reference to the volume of diluent used for reconstitution of dry powder for injection as per innovator product.
- Justify how you have performed pharmaceutical equivalence studies using the reference product of different strength.
- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting of Registration Board, which states that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".
- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"
- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Justify the weight variation limit of filled vial from1107-1152mg with reference to the claimed potency of both actives.
- Provide the Pharmacopeial reference of finished product specifications, since USP specs are mentioned in module 1, and USP does not contain any monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection. However, monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopeia.
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the document submitted in section 3.2.P.8 batch no. T-CSP-002 and T-CSP-003 has been manufactured on 02-2021, while stability study data sheet submitted in section 3.2.P.8.3 stated these batches were manufactured in sep-2021. Clarification required in this regard.
- Specify the batch size of all three stability batches.
- Justify the pH acceptance criteria (6.0-8.0) and water content acceptance limit (8.0-11%) set for drug product with the acceptance criteria mentioned on COA of drug substance by drug substance manufacturer i.e. 4.5-6.5 and NMT 3.0%. Elevation of pH and water content of drug product without any further processing of formulation needs to be justify with the pharmacopeial reference and innovator product.
- Assay content of both active should be separately calculated and mentioned as per pharmacopeial reference and innovator product.
- As per release specification of drug product acceptance criteria of assay is 90-110% while the stability data sheet represents that assay content should be between 90-115%. Justification is required regarding the variation in acceptance limit of assay content in various section of module-III.
- Justify why the sterility test is not included in the stability studies of the product.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

	• In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.	
Remarks of the Evaluator: In response of above shortcomings, firm has submitted a complete new CTD dossier with fee of Rs.7500/- in which drug substance was imported from a new source and accordingly data of trial batches of drug product manufactured from new source of drug substance has submitted. Newly submitted dossier has again evaluated and presented below before the Board for its consideration.		
457.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22144 dated 04/08/2022
	Details of fee submitted	PKR 7,500/-: dated 02/08/2022
	The proposed proprietary name / brand name	Cef-Slub Injection 2gm
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefoperazone sodium JP equivalent to Cefoperazone 1g Sterile Powder of Sulbactam sodium JP equivalent to Sulbactam 1g
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 2gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 2gm by Global Pharmaceuticals, Reg. No. 042555
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co. Ltd. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefoperazone sodium /sulbactam sodium Injection is present in JP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (2003FJ81NH, 2002FJ81NH, 2001FJ81NH)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product 2SUM (Cefoperazone Sodium + Sulbactam Sodium) 2g Injection of M/s. Healthtek Pvt. Ltd. Karachi, performing quality tests (Identification, Assay, constituted solution, BET & sterility test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Qilu Antibiotic Pharmaceutical Co. Ltd. China		
API Lot No.	2001FJ81NH		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRI004-01	TRI004-01	TRI004-01
Batch Size	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	26-01-2022	26-01-2022	26-01-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Qilu Antibiotics Pharmaceuticals Co. Ltd., China vide Dy. No. 11160/2021 DRAP Dated: 27-12-2021. Invoice attested vide Dy.no. 11160/2021 DRAP dated: 27-12-2021in which shipper was M/s. Shandong Luoxin Pharmaceuticals, China.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

<table>
<tr><th>Sr.no.</th><th>Section</th><th>Shortcomings/Observations</th></tr>
<tr><td>1.</td><td>3.2. S.4.1</td><td>Acceptance criteria of assay mentioned in specification of drug was not in accordance with JP monograph.
<table>
<tr><td>Assay limit mentioned in COA and specification of drug substance by both drug substance manufacturer and drug product manufacturer was Cefoperazone on anhydrous basis ≥43.5% and sulbactam on anhydrous basis ≥44.5%.</td><td>Assay acceptance criteria in accordance with JP monograph is “It contains not less than 90.0% and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24)”.</td></tr>
</table></td></tr>
<tr><td>2.</td><td>3.2. S.4.3</td><td>Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.</td></tr>
<tr><td>3.</td><td>3.2. S.5</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug substance.</td></tr>
<tr><td>4.</td><td>3.2. S.7</td><td>Firm has submitted only 6 months long term stability data of all three batches of drug substance.</td></tr>
<tr><td>5.</td><td>3.2P.2.1(a)(b)</td><td>Firm has not provided any details related to weight of powder filled per vial keeping in view the sodium content of both active substances.</td></tr>
<tr><td>6.</td><td>3.2.P.2.1(C)</td><td>Firm has not provided any details regarding the type of diluent, its composition, quantity or volume, specifications (as applicable) in which drug product has to be reconstitute before administration.</td></tr>
<tr><td>7.</td><td>3.2. P.2.2.1</td><td>Firm has submitted the pharmaceutical equivalence report in which the acceptance criteria of all the quality test was not in accordance with JP monograph:
<table>
<tr><th>Acceptance criteria in pharmaceutical equivalence report</th><th>Acceptance criteria in JP monograph</th></tr>
<tr><td>pH (6.0-8.8)</td><td>pH (4.5-6.5)</td></tr>
<tr><td>Assay (90%-110%)</td><td>Assay (It contains not less than 90.0 and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24).)</td></tr>
<tr><td>Bacterial Endotoxin Test (NMT 0.2 USP Endotoxin unit per mg)</td><td>Bacterial Endotoxin Test (Less than 0.060 EU/mg (potency).)</td></tr>
</table>
Further firm has not performed water content test and clarity and color of solution test which are also included in JP monograph.</td></tr>
</table>

8.	3.2. P.5.2	Firm has not submitted the analytical procedure used for testing of drug product.
9.	3.2.P.5.3	Analytical method verification report reflects that the assay has performed on UV method while the JP monograph recommends the HPLC method for assay of drug product.
10.	3.2.P.6	Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.
11.	3.2.P.8	Firm has not submitted following documents to support the stability data of drug product: • Reference of previous approval of applications with stability study data of the firm (if any) • Documents for the procurement of API with approval from DRAP (in case of import). • Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin. • Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.
12.	3.2.R	Firm has not submitted the copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Decision of 321st meeting of Registration Board:

- Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.
- Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
- Submit long term stability data of drug substance till the claimed shelf life.
- Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.
- Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.
- Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.
- Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug product.
- Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.
- Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Reply of the Firm:

Sr.no.	Decision	Response of the Firm

1.	Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.	Firm replied that "Ask the supplier about analytical method verification ,will be dispatched soon".	
2.	Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.	Firm replied that "By mistake it was attached, actual criteria of drug substance as per JP monograph".	
3.	COA of primary / secondary reference standard including source and lot number used for testing of drug substance.	Firm submitted the COA of USP primary reference standard	
4.	Submit long term stability data of drug substance till the claimed shelf life.	Firm replied that " Ask to supplier for long term stability, will be dispatched soon."	
5.	Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.	Firm submitted the formulation table in which only the material has been listed with the information that the API (cefoperazone sodium plus sulbactum sodium) was used 3% in excess, while the calculation of dispense quantity of API per vial was not submitted by the firm.	
6.	Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.	Firm submitted the pharmaceutical equivalence report in which all the quality test has been performed.	
7.	Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.	Submitted	
8.	Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.	Submitted	
9.	COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted	
10.	Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.	
11.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Not submitted	
12.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Not submitted	
13.	Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm submitted the fee of Rs.30,000/- vide slip no. 057382167110 dated 04-11-2022	

Decision of 323rd meeting of Registration Board:
Deferred for submission of following:

- Submit analytical method verification studies including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.
- COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
- Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.
- Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Response of the Firm:
Submit analytical method verification studies including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.
Firm submit the analytical verification report including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.

COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
Firm submit the copy of COA of primary reference standard of USP of both active substances, while the claimed specification of premixed powder of both API is JP specification.

Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.
In their reply firm only submitted the composition table mentioning the quantity of both active per vial i.e. Cefoperazone sodium+ Sulbactam sodium 2gm per vial, instead of giving complete calculation of weight of powder filled per vial keeping in view the sodium content of both active substances.

Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
Firm submit the valid GMP certificate of the Drug Substance manufacturer, which is valid till 13-12-2023.

Previously firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. Now the firm again submitted a new invoice, in which the Beneficiary is Qilu Pharmaceuticals Co. Ltd, China while the Manufacturer is M/s. The United Laboratories (Inner Mongolia), China quantity of 10kg is imported dated 21-06-2021, attested by DRAP vide dy.no.11160/2021 DRAP dated 27-12-2021.

While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.

Decision of 330th meeting of Registration Board:
Deferred for verification of DRAP attested documents related to the procurement of API.

Decision: Registration Board aceeded to the request of M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur for withdrawal of their above mentioned applications and declared them as disposed off.

Agenda of Evaluator PEC-XX

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

New DML

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

CLB in its 282nd meeting held on 31st August, 2021 has considered and approved the grant of DML by way of Formulation with following 3 sections:

- Tablet (General)
- Capsule Section (General)
- Oral Liquid (General)
- Capsule (Cephalosporin)
- Liquid injectable –vial &ampoule (General)
- Oral Dry powder suspension (Cephalosporin)
- Dry powder injectable (Cephalosporin)

458.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16126 dated 26-06-2023
	Details of fee submitted	PKR 30,000/- Dated 07/06/2023
	The proposed proprietary name / brand name	**Azdir 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin dihydrate eq to Azithromycin…..500mg
	Pharmacotherapeutic Group of (API)	Macrolide
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	6’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azithromycin 500mg tablet USFDA approved
	For generic drugs (me-too status)	Azomax 500mg tablet by M/s AGP pharma Reg No 112798
	Name and address of API manufacturer.	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not Provided
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against **Azomax 500mg tablet** by **AGP (Batch No T8760, Exp date 12-2024).** Quality parameters such as appearance, average weight, dissolution, content uniformity, Disintegration, hardness and assay against Test product. Firm has submitted CDP results of **Azithromycin 250mg capsule (instead of 500mg tablet)** against the **Azomax 250mg capsule (Batch No T8838)** in Acid media (pH 1.0-1.2) acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
API Lot No..Batch number	AZM2208004
Description of Pack (Container closure system)	Alu-Alu blister with unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	TTR025	TTR026	TTR027
Batch Size	600 tab	600 tab	600 tab
Manufacturing Date	12/22	12/22	12/22
Date of Initiation	16/12/22	16/12/22	16/12/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*	
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by DRAP.	Firm has provided copy of GMP certificate based on inspection dated 03-03-2023 issued by DRAP Pakistan	Complied
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied

	4.	**3.2.S.4** Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.	Analytical Method Verification studies of Drug substance performed by the Drug Substance manufacturer is submitted	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer yet to be provided	
	5.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.	Provided	Complied	
	6.	**3.2.S.7** Provide stability data of Drug Substance (both Accelerated and Real time) of 3 batches.	Stability data of 3 batches: AZM2101001 AZM2101002 AZM2101003 As per zone IV-A conditions Real time for 9 months Accelerated for 6 months	Complied	
	7.	**3.2.P.2.2.1** Perform CDP of applied product (azithromycin 500mg tablet). CDP results of **Azithromycin 250mg capsule** (Batch No T8760) have been submitted (against the Azomax 250mg capsule Batch No T8838).	CDP report against **Azomax 500mg Tablet by AGP Ltd** Batch No T8760, Exp date 12/2024 is provided.	Complied	
	8.	**3.2.P.5** Assay method is not as per USP 2023 (chromatographic conditions, quantity of diluents/mobile phase etc) adopt assay as per USP 2023 and submit accordingly.	Assay method as per USP 2023 has been submitted		
	9.	**3.2.P.8** Provide procurement document/commercial invoice wherein quantity, batch no and date of purchase should be mentioned**.**	Purchase invoice No CP22-11024 dated 08 Dec 2022 is provided wherein Azithromycin Batch No AZM2208004 is mentioned	Complied	
	10.	**3.2.P.8** Provide stability data of Drug Product (both Accelerated and Real time) for 6th month and onward all 3 batches.	Only summary data sheet is provided for 6th month data (both Accelerated and Real time)	CoA and chromatograms to be provided.	

Decision: Deferred the request for submission of following documents:

a) **Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.**
b) **CoA and chromatograms of stability data of all 3 batches of Drug Product (both Accelerated and Real time) for 6th month.**

459.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16125 dated 26-06-2023
	Details of fee submitted	PKR 30,000/- Dated 07/06/2023
	The proposed proprietary name / brand name	**Azdir 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Azithromycin dihydrate eq to Azithromycin…. 250mg
	Pharmacotherapeutic Group of (API)	Macrolide
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	6's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax 250mg capsule Pfizer Limited MHRA approved
	For generic drugs (me-too status)	Azomax 250mg capsule by M/s AGP pharma Reg No 112797
	Name and address of API manufacturer.	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not Provided
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against **Azomax 250mg capsule** by **AGP (Batch No T8838).** Quality parameters such as appearance, average weight, dissolution, content uniformity, Disintegration and assay against Test product. Firm has submitted CDP results of **Azithromycin 500mg tablet** (instead of 250mg capsule) against the **Azomax 500mg Tablet (Batch No T8760)** in Acid media (pH 1.0-1.2) acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.		
API Lot No..Batch number	AZM2208004		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CTR025	CTR026	CTR027
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	12/22	12/22	12/22

Date of Initiation	16/12/22	16/12/22	16/12/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*	
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by DRAP.	Firm has provided copy of GMP certificate based on inspection dated 03-03-2023 issued by DRAP Pakistan	Complied
3.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
4.	**3.2.S.4** Analytical method verification study of Drug Substance to be performed by Drug Product manufacturer.	Analytical Method Verification studies of Drug substance performed by the Drug Substance manufacturer is submitted	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer yet to be provided
5.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.	Provided	Complied

	6.	**3.2.S.7** Provide stability data of Drug Substance (both Accelerated and Real time) of 3 batches.	Stability data of 3 batches: AZM2101001 AZM2101002 AZM2101003 As per zone IV-A conditions Real time for 9 months Accelerated for 6 months	Complied	
	7.	**3.2.P.2.2.1** Perform CDP of applied product (azithromycin 250mg capsule) CDP results of **Azithromycin 500mg tablet** have been submitted (against Azomax 500mg Tablet Batch No T8760).	CDP report against **Azomax 250mg capsule by AGP Ltd** Batch No T8838, Exp date 12/2024 is provided.	Complied	
	8.	**3.2.P.5** Water content test has not been performed as per USP.	*Water content test has been performed by Karl fischer method*	Performance report has not been provided	
	9.	**3.2.P.8** Provide procurement document/commercial invoice wherein quantity, batch no and date of purchase should be mentioned**.**	Purchase invoice No CP22-11024 dated 08 Dec 2022 is provided wherein Azithromycin Batch No AZM2208004 is mentioned	Complied	
	10.	**3.2.P.8** Provide stability data of Drug Product (both Accelerated and Real time) for 6th month and onward all 3 batches.	Only summary data sheet is provided for 5th month data (both Accelerated and Real time)	CoA and chromatograms to be provided.	

Decision: Deferred the request for submission of following documents:

a) **Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.**
b) **CoA and chromatograms of stability data of all 3 batches of Drug Product (both Accelerated and Real time) for 6th month.**
c) **Performance report Water content test as per USP**

460.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying "Capsule (Cephalosporin) section".

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23871 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 23/08/2023
	The proposed proprietary name / brand name	**Qadroxil 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefadroxil monohydrate eq. to Cefadroxil 500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin antibacterial
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	12's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefadroxil 500mg capsule by Sandoz UK MHRA approved
	For generic drugs (me-too status)	Duricef 500mg capsule M/s *GSK Pakistan* Reg No 008013
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months Batches: 00224/001/2009 00224/002/2009 00224/003/2009
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures,validation of analytical procedures, batch analysis,justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the brand leader that is Duricef 500mg capsule of M/s GSK Pakistan Ltd (**Batch No PG4S, Exp date 01-2026)** performing quality tests (Identification, Assay, Dissolution, water content, average weight and Uniformity of dosage form). CDP has been performed against **Duricef 500mg capsule** by M/s GSK Pakistan Ltd in pH 1.2, pH 4.5 & Phosphate Buffer pH 6.8. The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/**s** Pharmagen Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore		
API Lot No..Batch number	002240/22-12/010		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CTR052	CTR053	CTR054
Batch Size	720 cap	720 cap	720 cap
Manufacturing Date	01/23	01/23	01/23
Date of Initiation	23-01-2023	23-01-2023	23-01-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate based on inspection dated 18-11-2022 issued by DRAP Pakistan
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided commercial invoice No 1601 dated 10.01.2023 wherein Lot No 002240/22-12/010 was mentioned confirming purchase of 1 kg Cefadroxil (compacted)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*	
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
3.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer to be provided.	Analytical Method Verification studies of Drug substance performed by the Drug substance manufacturer	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer yet to be submitted
4.	**3.2.P.5** Justify assay limit mentioned i.e 90-110% instead of 90-120% (as mentioned in USP).	*The assay limit is 90-120% (as mentioned in USP). The limit mentioned in dossier 90-110% is writing mistake.*	

Decision: Approved. Firm will provide Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer before issuance of registration letter.

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
461.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying "Oral dry powder suspension (Cephalosporin) section".
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23869 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 23/08/2023
	The proposed proprietary name / brand name	**Qadroxil 125mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml reconstituted suspension contains: Cefadroxil monohydrate eq. to Cefadroxil 125mg
	Pharmacotherapeutic Group of (API)	Cephalosporin antibacterial
	Pharmaceutical form of applied drug	Dry Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefadroxil 125mg/5ml Dry Suspension ALKALOID-INT Slovenia USFDA
	For generic drugs (me-too status)	Duricef 125mg/5ml Dry suspension M/s *GSK Pakistan* Reg No 008014
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months Batches: 00224/001/2009 00224/002/2009 00224/003/2009
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures,validation of analytical procedures, batch analysis,justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the brand leader that is Duricef 125mg/5ml Dry suspension of M/s GSK Pakistan Ltd (**Batch No SV5H, Exp date 02-2026)** performing quality tests (Identification, Assay, Dissolution, deliverable volume, pH, water content and Uniformity of dosage form). CDP has been performed against **Duricef 125mg capsule** by M/s GSK Pakistan Ltd instead of dry suspension in pH 1.2, pH 4.5 & Phosphate Buffer pH 6.8. The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API	**M/s** Pharmagen Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore	

API Lot No..Batch number	**002230/22-12/009**		
Description of Pack (Container closure system)	Amber glass bottle sealed with Polyethylene and Aluminium cap		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TDS01	TDS02	TDS03
Batch Size	50 bottles	50 bottles	50 bottles
Manufacturing Date	01/23	01/23	01/23
Date of Initiation	23-01-2023	23-01-2023	23-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate based on inspection dated 18-11-2022 issued by DRAP Pakistan
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided commercial invoice No 1597 dated 07.01.2023 wherein Lot No 002230/22-12/009 was mentioned confirming purchase of 1 kg Cefadroxil (micronized)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer to be provided.
4.	**3.2.P.2** Quantity of API mentioned in Batch formula i.e 1575mg per unit ml to be justified
5.	**3.2.P.2** Specify type of glass bottle and provide suitability testing/quality testing (as per pharmacopeia) of container closure system
6.	**3.2.P.2** Provide details regarding volume of diluent to be used for reconstitution to achieve label claim 125mg/5ml along with weight/ml calculation with reference to innovator's product

	7.	**3.2.P.5** Justify assay limit mentioned i.e 95-102% w/w instead of 90-120% (as mentioned in USP.
	8.	**3.2.P.2.2.1** CDP has been performed against **Duricef 125mg capsule** instead of **Cefadroxil 125mg/5ml Dry suspension.** Perform CDP against Duricef 125mg/5ml suspension and submit report accordingly.
	9.	**3.2.P.8** In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)

Firm has submitted reply as follows:

Sr.#	Reply
1.	*New DML has been granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*
2.	Batch Manufacturing Record (BMR) for all the batches of drug product (for which stability studies data is provided) has been provided
3.	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer yet to be provided.
4.	Quantity of API mentioned in Batch formula i.e 1575mg has been justified (per unit bottle).
5.	Type of glass bottle is specified as "soda lime" however suitability testing/quality testing (as per pharmacopeia) of container closure system are not provided.
6.	Details regarding volume of diluent to be used for reconstitution to achieve label claim is provided as 40ml (2 scoops of 20ml) water and weight/ml of applied formulation is 1.095g/ml while weight of content per ml of Duricef 125mg/5ml is 1.160g/ml
7.	The assay limit mentioned in dossier i.e 95-102% w/w was typographic erroe while actual assay limit is 90-120% (as mentioned in USP).
8.	CDP has been performed against **Duricef 125mg/5ml suspension** and report is submitted accordingly. **Batch No: SV5H** **Mfg date: 02/2023**
9.	In use stability data (reconstituted form) is provided for the period of 14 days (at both room temp and refrigerator)

Decision: Approved. Firm will provide following before issuance of registration letter.

i. **Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.**
ii. **Suitability testing/quality testing (as per pharmacopeia) of container closure system (soda lime glass bottle) to be provided before issuance of registration letter**

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

462.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying "Oral dry powder suspension (Cephalosporin) section".
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23870 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 23/08/2023
	The proposed proprietary name / brand name	**Qadroxil 250mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml reconstituted suspension contains: Cefadroxil monohydrate eq. to Cefadroxil 250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin antibacterial
	Pharmaceutical form of applied drug	Dry Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefadroxil 250mg/5ml Dry Suspension ALKALOID-INT Slovenia USFDA
	For generic drugs (me-too status)	Duricef 250mg/5ml Dry suspension M/s *GSK Pakistan* Reg No 010057
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months Batches: 00224/001/2009 00224/002/2009 00224/003/2009
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the brand leader that is Duricef 250mg/5ml Dry suspension of M/s GSK Pakistan Ltd (**Batch No CK2A, Exp date 08-2025)** performing quality tests (Identification, Assay, Dissolution, deliverable volume, pH, water content and Uniformity of dosage form). CDP has been performed against **Duricef 250mg capsule** by M/s GSK Pakistan Ltd instead of dry suspension in pH 1.2, pH 4.5 & Phosphate Buffer pH 6.8. The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore		
API Lot No..Batch number	**002230/22-12/009**		
Description of Pack (Container closure system)	Amber glass bottle sealed with Polyethylene and Aluminium cap		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TDS04	TDS05	TDS06

Batch Size	50 bottles	50 bottles	50 bottles
Manufacturing Date	01/23	01/23	01/23
Date of Initiation	23-01-2023	23-01-2023	23-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate based on inspection dated 18-11-2022 issued by DRAP Pakistan
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided commercial invoice No 1597 dated 07.01.2023 wherein Lot No 002230/22-12/009 was mentioned confirming purchase of 1 kg Cefadroxil (micronized)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer to be provided.
4.	**3.2.P.2** Quantity of API mentioned in Batch formula i.e 3150mg per unit ml to be justified
5.	**3.2.P.2** Specify type of glass bottle and provide suitability testing/quality testing (as per pharmacopeia) of container closure system
6.	3.2.P.2 Provide details regarding volume of diluent to be used for reconstitution to achieve label claim 250mg/5ml along with weight/ml calculation with reference to innovator's product
7.	**3.2.P.2.2.1** CDP has been performed against **Duricef 250mg capsule** instead of **Cefadroxil 250mg/5ml Dry suspension.** Perform CDP against Duricef 250mg/5ml suspension and submit report accordingly.
8.	**3.2.P.5** Justify assay limit mentioned i.e 95-102% w/w instead of 90-120% (as mentioned in USP.
9.	**3.2.P.8** In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)

Firm has submitted reply as follows:

Sr.#	Reply

	1.	*New DML has been granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*	
	2.	Batch Manufacturing Record (BMR) for all the batches of drug product (for which stability studies data is provided) has been provided	
	3.	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer yet to be provided.	
	4.	Quantity of API mentioned in Batch formula i.e 3150mg has been justified (per unit bottle).	
	5.	Type of glass bottle is specified as "soda lime" however suitability testing/quality testing (as per pharmacopeia) of container closure system are not provided.	
	6.	Details regarding volume of diluent to be used for reconstitution to achieve label claim is provided as 40ml (2 scoops of 20ml) water and weight/ml of applied formulation is 1.100g/ml while weight of content per ml of Duricef 250mg/5ml is 1.160g/ml	
	7.	The assay limit mentioned in dossier i.e 95-102% w/w was typographic erroe while actual assay limit is 90-120% (as mentioned in USP).	
	8.	CDP has been performed against **Duricef 250mg/5ml suspension** and report is submitted accordingly. **Batch No: CK2A** **Mfg date: 01/2023**	
	9.	In use stability data (reconstituted form) is provided for the period of 14 days (at both room temp and refrigerator)	

Decision: Approved. Firm will provide following before issuance of registration letter.

i. **Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.**
ii. **Suitability testing/quality testing (as per pharmacopeia) of container closure system (soda lime glass bottle) to be provided before issuance of registration letter**

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

463.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27743 dated 28-11-2023
	Details of fee submitted	PKR 30,000/- Dated 25/10/2023
	The proposed proprietary name / brand name	**Danzol 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dual Delayed release pellets of Dexlansoprazole eq to Dexlansoprazole..... 30mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	As per innovator specification
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 30mg DDR capsule USFDA approved
	For generic drugs (me-too status)	Dextop 30mg capsule by M/s Searl Company Ltd Reg No 086978
	Name and address of API manufacturer.	M/s Winbrain Research Laboratories Plot No 69/I Block B, Phase I-II, Industrial Estate. Hattar. Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. T-01 T-02 T-03 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures,validation of analytical procedures, batch analysis,justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Dextop 30mg capsule** by **Searl company Ltd (Batch No FRD013).** Quality parameters such as appearance, average weight, water content, dissolution content uniformity and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Dextop 30mg capsule (Batch No FRD013, Exp date 06/24)** in Acid media (pH 1.0-1.2) 2 hours, Buffer stage I (pH 5.5) 1 hour, Buffer stage II (pH 7.0) 2 hours. The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method validation study reports for drug substance as well as product.

STABILITY STUDY DATA

Manufacturer of API	M/s Winbrain Research Laboratories Plot No 69/I Block B, Phase I-II, Industrial Estate. Hattar. Pakistan.		
API Lot No..Batch number	DLP-045/2022		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CTR019	CTR020	CTR021
Batch Size	810 cap	810 cap	810 cap
Manufacturing Date	11/22	11/22	11/22
Date of Initiation	26/11/22	26/11/22	26/11/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate has been provided dated 06.05.2021 based on inspection dated 05.05.2021 (valid till three years) Manufacturing facility for pelletization of Dexlansoprazole pellets is mentioned.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Dissolution testing performed by finished product manufacturer on DDR pellets were as follows:

Dissolution parameters	**Specification**
Acid stage (Stage I)	
Apparatus	**USP I**
Medium	0.1N HCl
Volume	500ml
RPM	**100**
Sample interval	120 minutes
Limit	NMT 10%
Buffer stage (Stage I)	
Apparatus	**USP I**
Medium	**pH 5.5**
Volume	**900ml**
RPM	**100**
Sample interval	60 minutes
Limit	22.5%-40%
Buffer stage (Stage II)	
Apparatus	**USP I**
Medium	**pH 7.0**
Volume	900ml
RPM	**100**
Sample interval	40 min, 60 min, 105 min and 120 min
Limit	30-60% 40-70% NLT 60% NLT 75%

Dissolution parameters of innovator product (Dexilant) are as follows:

Sr.#	**Observations**
1.	Provide updated GMP status of finished product manufacturer
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	**3.2.S.4** Justification to be provided for selection of dissolution parameters i.e dissolution medium, volume of dissolution medium and rpm etc

4.	**3.2.S.7** Provide real time stability data of pellets up to shelf life. Already submitted data is for the period of **6 months only.**
5.	**3.2.P.8** Provided invoice/ document for procurement of API wherein date and batch no of API should be mentioned.

Reply:

Sr.#	**Reply**
1.	*New DML has been granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*
2.	Batch Manufacturing Record (BMR) for all the batches of drug product (for which stability studies data is provided) has been provided
3.	Dissolution parameters i.e dissolution medium, volume of dissolution medium and rpm etc have been adopted as provided by Pellet manufacturer in DMF, moreover same parameters have been mentioned in "Draft guidance on Dexlansoprazole (USFDA)"
4.	Real time stability data of pellets up to 24 months has been provided for following three batches: DEX 005 DEX 006 DEX 007
5.	Invoice for procurement of Dexlansoprazole dated 06.10.2022 and batch no (DLP-045/2022) is provided.

Remarks: Dissolution parameters such as dissolution medium, volume of dissolution medium and rpm etc are in accordance to parameters approved by Registration Board in 277th meeting (held on 27th -29th December, 2017).

Decision: Approved as per innovators sepecifications.

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

464.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**

	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 27744 dated 28-11-2023
	Details of fee submitted	PKR 30,000/- Dated 25/10/2023
	The proposed proprietary name / brand name	**Danzol 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dual Delayed release pellets of Dexlansoprazole eq to Dexlansoprazole..... 60mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	As per innovator specification
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 60mg DDR capsule USFDA approved
	For generic drugs (me-too status)	Dextop 60mg capsule by M/s Searl Company Ltd Reg No 086979
	Name and address of API manufacturer.	M/s Winbrain Research Laboratories Plot No 69/I Block B, Phase I-II, Industrial Estate. Hattar. Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. T-01 T-02 T-03 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Dextop 60mg capsule** by **Searl company Ltd (Batch No FSD009).** Quality parameters such as appearance, average weight, water content, dissolution content uniformity and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Dextop 30mg capsule (Batch No FSD009, Exp date 05/24)** in Acid media (pH 1.0-1.2) 2 hours, Buffer stage I (pH 5.5) 1 hour, Buffer stage II (pH 7.0) 2 hours. The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method validation study reports for drug substance as well as product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Winbrain Research Laboratories Plot No 69/I Block B, Phase I-II, Industrial Estate. Hattar. Pakistan.
API Lot No..Batch number	DLP-045/2022
Description of Pack (Container closure system)	Alu-Alu blister with unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CTR022	CTR023	CTR024
Batch Size	750 cap	750 cap	750 cap
Manufacturing Date	11/22	11/22	11/22
Date of Initiation	26/11/22	26/11/22	26/11/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate has been provided dated 06.05.2021 based on inspection dated 05.05.2021 (valid till three years) Manufacturing facility for pelletization of Dexlansoprazole pellets is mentioned.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided
Remarks of Assessor:		

Dissolution testing performed by finished product manufacturer on DDR pellets were as follows:

Dissolution parameters	**Specification**
Acid stage (Stage I)	
Apparatus	**USP I**
Medium	0.1N HCl
Volume	500ml
RPM	**100**
Sample interval	120 minutes
Limit	NMT 10%
Buffer stage (Stage I)	
Apparatus	**USP I**
Medium	**pH 5.5**
Volume	**900ml**
RPM	**100**
Sample interval	60 minutes
Limit	22.5%-40%
Buffer stage (Stage II)	
Apparatus	**USP I**

Medium	**pH 7.0**
Volume	900ml
RPM	**100**
Sample interval	40 min, 60 min, 105 min and 120 min
Limit	30-60% 40-70% NLT 60% NLT 75%

Dissolution parameters of innovator product (Dexilant) are as follows:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	**3.2.S.4** Justification to be provided for selection of dissolution parameters i.e dissolution medium, volume of dissolution medium and rpm etc
4.	**3.2.S.7** Provide real time stability data of pellets up to shelf life. Already submitted data is for the period of **6 months only.**
5.	**3.2.P.8** Provided invoice/ document for procurement of API wherein date and batch no of API should be mentioned.

Sr.#	Reply
1.	*New DML has been granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*
2.	Batch Manufacturing Record (BMR) for all the batches of drug product (for which stability studies data is provided) has been provided
3.	Dissolution parameters i.e dissolution medium, volume of dissolution medium and rpm etc have been adopted as provided by Pellet manufacturer in DMF, moreover same parameters have been mentioned in "Draft guidance on Dexlansoprazole (USFDA)"
4.	Real time stability data of pellets up to 24 months has been provided for following three batches: DEX 005 DEX 006 DEX 007
5.	Invoice for procurement of Dexlansoprazole dated 06.10.2022 and batch no (DLP-045/2022) is provided.

Remarks: Dissolution parameters such as dissolution medium, volume of dissolution medium and rpm etc are in accordance to parameters approved by Registration Board in 277th meeting (held on 27th -29th December, 2017).

Decision: approved As per innovator specification.

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

465.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23864 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 10/03/2023
	The proposed proprietary name / brand name	**Dicloqad SR 100mg capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Sustained release pellets of Diclofenac Sodium 100mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	BP
	Proposed Pack size	2x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Diclofenac sodium 100mg Modified Release capsule Glenwood GmbH Pharmazeutische Germany HPRA approved
	For generic drugs (me-too status)	**Product:** Mobikare SR100mg capsules M**anufacturer:** M/S *Barrett Hodgson Pakistan* (Pvt) Ltd (Reg No 029393)
	Name and address of API manufacturer.	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. DFS-SR-001 DFS-SR-002 DFS-SR-003 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Comparator product that is Mobikare SR100mg capsule (Batch No D3048, Exp date 10/2024) of M/s *Barrett Hodgson Pakistan* (Pvt.) Ltd performing quality tests (Identification, Assay, Dissolution, LOD, Average weight and Uniformity of dosage form). CDP has been performed against the same brand that is Mobikare SR 100mg capsules of M/S *Barrett Hodgson Pakistan* (Pvt.) Ltd in pH 1.2, & Phosphate Buffer pH 6.8 (up to 8 hours). The values for f1 and f2 are in the acceptable range.
	Analytical method validation of product	Firm has submitted analytical method validation study reports for drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan		
API Lot No..Batch number	DFS-32-SR-009		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CTR037	CTR038	CTR039
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	01/23	01/23	01/23
Date of Initiation	17/01/23	17/01/23	17/01/23
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate dated 04.07.2019 issued by DRAP is provided. Based on inspection dated 03.07.2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of invoice (Invoice# 23010247-SG) dated 06-01-2023, with received quantity i.e. 2kg) for the purchase of Diclofenac sodium SR pellets 32% (Batch No DFS-32-SR-009) from M/s Surge Laboratories, Pakistan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by DRAP. Moreover, approval for manufacturing **Diclofenac sodium SR pellets** to be provided.
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	**3.2.S.4** Under shelf life specification of pellets the dissolution /release profile in phosphate buffer medium (pH 6.8) is mentioned as:

		• **30-65%** of labelled amount of Diclofenac sodium pellets should be released after 3 hours • NLT 70% of labelled amount of Diclofenac sodium pellets should be released after 8 hours While content of enteric coated pellets as mentioned in reference formulation is 25% (25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets)
	5.	**3.2.P.2** The excipients used by pellet manufacturer such as Disodium Hydrogen Phosphate and HPMC have not been found in innovator/reference product. Drug-excipients compatibility study is required. Moreover, excipients such as Microcrystalline cellulose, Methacrylic acid copolymer, colloidal anhydrous silica, propylene glycol, sodium hydroxide and Triethylcitrate have been used in reference product but not found in applied formulation. Clarify implication of not using said ingredients.
	6.	**3.2.P.2** The label claim / formulation of reference product is as follows: Difene 100 mg Dual Release Capsule/modified release capsule Each capsule contains: Diclofenac sodium 100mg in a modified release formulation (25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets) Justify applied formulation in light of above mentioned reference formulation. Moreover, also prove that comparator (generic version) against which pharmaceutical equivalence/CDP was performed is dual release capsule.
	7.	**3.2.P.5** Finished product specification mentioned on Form5F as BP while specifications mentioned under section 3.2.P.5 as USP 43. However, modified release/dual delayed release capsule of Diclofenac sodium are not found in any official monograph. Provide correct reference of finished product specification accordingly.
	8.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.

Reply:

Sr.#	Reply
1.	*New DML has been granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*
2.	Valid Good Manufacturing Practice (GMP) certificate of Pellet manufacturer based on inspection dated 25.08.2022 issued by DRAP. Wherein approval for manufacturing **Diclofenac sodium SR pellets** and **Diclofenac sodium enteric coated pellets** is provided.
3.	Batch Manufacturing Record (BMR) for all the batches of drug product (for which stability studies data is provided) has been provided.
4.	*This is because our product complies with BP specification of Diclofenac sodium Prolong Release capsules***.** *The reference product and our pellets both are enteric coated and sustained release in nature and complying to BP.*
5.	Drug-excipients compatibility study is provided by Binary method. There is no significant change occurs during compatibility studies.
6.	*The applied formulation is in light of Diclofenac Prolong Release capsule of BP monograph and the comparator product against which CDP/Pharmaceutical equivalence was performed is diclofenac SR pellets in accordance to BP*

	7.	*Finished product specification mentioned on Form5F as BP because Diclofenac Prolong release capsule is available in official monograph of BP 2023. while specifications mentioned under section 3.2.P.5 as USP 43 is writing mistake.* *Qadir Pharmaceutical Label claim is "Diclofenac Sustained Release or Prolong release" as mentioned in monograph of BP 2023.*	
	8.	COA of primary / secondary reference standard including source and lot number is provided.	

Remarks:

- The label claim / formulation of RRA (HPRA) approved formulation is as follows:

Difene 100 mg Dual Release Capsule/modified release capsule

Each capsule contains:

Diclofenac sodium 100mg in a modified release formulation (25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets)

While firm claimed to comply BP specification. However, in BP available formulation is "Diclofenac Sustained Release capsule" Hence clarification regarding applied specification is required.

- The above mentioned RRA approved formulation contains both type of pellets 25mg in the form of enteric coated release pellets and 75mg in the form of sustained release pellets) while manufacturing process flow diagram provided by firm revealed that Placebo pellets were firstly coated by Drug Loading solution followed by seal coating (HPMC). Seal coated pellets are further coated by Enteric Dispersion followed by drying and packaging.

Hence it is evident that contrary to RRA approved formulation whole proportion of Drug was formulated to be sustained releae and delayed release (by way of enteric coating) simultaneously. Hence applied formulation need to be justified in light of RRA approved formulation. Furthermore, following drug release pattern need to be justified accordingly:

Acid medium (0.1 M HCl)

- NMT 10% 0.1 M HCl after 120 min

Buffer medium (pH 6.8)

- **30-65%** of labelled amount of Diclofenac sodium pellets should be released after 3 hours
- NLT 70% of labelled amount of Diclofenac sodium pellets should be released after 8 hours

Decision: Registration Board deferred the case for clarification regarding applied formulation whether Modified release capsule (as approved in HJPRA Irland) or Prolong Release Capsule (as provided in BP) and accordingly the applied specification.

466.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23867 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 10/08/2023
	The proposed proprietary name / brand name	**Qadxet 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Delayed release pellets of Duloxetine HCl eq to Duloxetine…..... 30mg
	Pharmacotherapeutic Group of (API)	Serotonin and Noradrenaline Reuptake Inhibitor
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	14's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Aspire Pharma Ltd, UK
	For generic drugs (me-too status)	Dulan 30mg capsule by M/s Hilton pharma Reg No 055447
	Name and address of API manufacturer.	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. DXP-17-001 DXP-17-002 DXP-17-003 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Cymbalta 30mg capsule** by **Eli-Lilly Pakistan Pvt Ltd (Batch No D462328A).** Quality parameters such as appearance, average weight, water content, dissolution content uniformity and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Cymbalta 30mg capsule (Batch No D462328A, Exp date 05/24)** in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan		
API Lot No..Batch number	DXP-17-119		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CTR029	CTR030	CTR031
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	01/23	01/23	01/23

Date of Initiation	14/01/23	14/01/23	14/01/23
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of invoice (Invoice# 23010247-SG) dated 06-01-2023, with received quantity i.e. 2kg) for the purchase of Duloxetine HCl pellets 17.65% (Batch No DXP-17-119) from M/s Surge Laboratories, Pakistan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet*.	
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by DRAP.	GMP inspection report dated 25.08.2022 has been submitted (valid for two years)	Complied
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
4.	**3.2.S.4** Analytical method of Drug Substance/Pellets has not been found as per USP (Chromatographic conditions, assay and dissolution method etc). Clarify the source of submitted method.	Not provided	Not complied
5.	The excipients used by pellet manufacturer such as Mannitol, Methacrylic acid co-polymer. Triethyl citrate and Magnesium stearate have not been found in	Drug-excipients compatibility study has been provided (binary method). There is no significant change	Complied

		innovator/reference product. Drug-excipients compatibility study is required.	occurs during compatibility study,		
	6.	**3.2.P.2** Quantity of API mentioned per unit capsule (170mg for 30mg capsule and 340mg for 60mg capsule) to be justified (w.r.t salt factor/ potency adjustment).	Quantity of API mentioned per unit capsule (170mg for 30mg capsule and 340mg for 60mg capsule) is due to potency of API i.e 17.72% which is 170mg and 340mg in round figure	Salt factor has not been calculated (Duloxetine HCl 33.73mg eq to Duloxetine 30mg similarly Duloxetine HCl 67.37mg eq to Duloxetine 60mg).	
	7.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.	Provided	Complied	

Decision: Approved. Registration letter will be issued upon submission of correction of quantity of API in Batch formula by calculating salt factor.

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

467.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23868 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 10/08/2023
	The proposed proprietary name / brand name	**Qadxet 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Delayed release pellets of Duloxetine HCl eq to Duloxetine…..... 60mg
	Pharmacotherapeutic Group of (API)	Serotonin and Noradrenaline Reuptake Inhibitor

	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP
	Proposed Pack size	14's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Aspire Pharma Ltd, UK
	For generic drugs (me-too status)	Dulan 60mg capsule by M/s Hilton pharma Reg No 055448
	Name and address of API manufacturer.	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. DXP-17-001 DXP-17-002 DXP-17-003 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Cymbalta 60mg capsule** by **Eli-Lilly Pakistan Pvt Ltd (Batch No D521211).** Quality parameters such as appearance, average weight, water content, dissolution content uniformity and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Cymbalta 60mg capsule (Batch No Batch No D521211, Exp date 01/25)** in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan		
API Lot No..Batch number	DXP-17-119		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CTR034	CTR035	CTR036
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	01/23	01/23	01/23
Date of Initiation	14/01/23	14/01/23	14/01/23
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of invoice (Invoice# 23010247-SG) dated 06-01-2023, with received quantity i.e. 2kg) for the purchase of Duloxetine HCl pellets 17.65% (Batch No DXP-17-119) from M/s Surge Laboratories, Pakistan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided

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

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet*.	
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by DRAP.	GMP inspection report dated 25.08.2022 has been submitted (valid for two years)	Complied
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
4.	**3.2.S.4** Analytical method of Drug Substance/Pellets has not been found as per USP (Chromatographic conditions, assay and dissolution method etc). Clarify the source of submitted method.	Not provided	Not complied
5.	The excipients used by pellet manufacturer such as Mannitol, Methacrylic acid co-polymer. Triethyl citrate and Magnesium stearate have not been found in innovator/reference product. Drug-excipients compatibility study is required.	Drug-excipients compatibility study has been provided (binary method). There is no significant change occurs during compatibility study,	Complied
6.	**3.2.P.2** Quantity of API mentioned per unit capsule (170mg for 30mg capsule and 340mg for 60mg capsule) to be justified (w.r.t salt factor/ potency adjustment).	Quantity of API mentioned per unit capsule (170mg for 30mg capsule and 340mg for 60mg capsule) is due to potency of API i.e 17.72% which is 170mg and 340mg in round figure	Salt factor has not been calculated (Duloxetine HCl 33.73mg eq to Duloxetine 30mg similarly Duloxetine HCl 67.37mg eq to Duloxetine 60mg).
7.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.	Provided	Complied

Decision: Approved. Registration letter will be issued upon submission of correction of quantity of API in Batch formula by calculating salt factor.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
468.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying "Oral Liquid (General) section".
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16127 dated 28-06-2023
	Details of fee submitted	PKR 30,000/- dated 08/05/2023
	The proposed proprietary name / brand name	**Qad-fen 100mg/5ml suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension contains: Ibuprofen…..... 100mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Oral Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	90ml and 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Brufen 100mg/5ml by Mylan MHRA approved
	For generic drugs (me-too status)	Brufen 100mg/5ml by M/s Abbott Laboratories Pakistan Ltd. Reg No 004595
	Name and address of API manufacturer.	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months **Batches:** IBP1806001, IBP1806002, IBP1806003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the brand leader that is **Brufen 100mg/5ml suspension** by M/s Abbott Laboratories Pakistan (**Batch No 4823738Q, Mfg date 01-2023)** performing quality tests (Identification, Assay, Dissolution, deliverable volume, pH, water content and Uniformity of dosage form). CDP has been performed against same product **Brufen 100mg/5ml suspension** by M/s Abbott Laboratories Pakistan in pH 1.2, pH 4.5 & Phosphate Buffer pH 6.8. The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.	

API Lot No..Batch number	IBP2211030		
Description of Pack (Container closure system)	90ml and 120ml PET bottle amber colour in unit carton 1x1's		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LS010	LS011	LS012
Batch Size	50 bottles	50 bottles	50 bottles
Manufacturing Date	12/22	12/22	12/22
Date of Initiation	21-12-2022	21-12-2022	21-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate based on inspection dated 14-07-2016 issued by DRAP Pakistan
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*	
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / APImanufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of GMP certificate based on inspection dated 03-03-2023 issued by DRAP Pakistan	Complied
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is	Provided	Complied

		provided in Module 3 section 3.2.P.8.3			
	4.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer tobe provided.	Analytical Method Verification studies of Drug substance performed by the Drug Substance manufacturer is submitted	Analytical Method Verification studies of Drug substance performed by the Drug Product manufacture yet to be provided	
	5.	**3.2.P.2** Provide suitability testing/quality testing (as per pharmacopeia) of container closure system (PET bottle)	Not provided	Quality testing method is submitted as per USP however test result /performance report yet to be submitted.	
	6.	**3.2.P.5** Justify chromatographic conditions adopted in assay since chromatographic conditions mentioned in USP as: Detector: UV 254 nm. Flow rate: 1.0 mL/min While chromatographic conditions adopted by firm as: Detector: UV 220 nm Flow rate: 2 mL/min	Firm has provided reference of USP38-NF33 wherein chromatographic conditions mentioned were as follows: Detector: UV 220 nm Flow rate: 2 mL/min	chromatographic conditions to be adopted as per latest version of monograph USP 2023 as follows: Detector: UV 254 nm. Flow rate: 1.0 mL/min	
	7.	**3.2.P.8** Chromatograms of dissolution study has not been provided.	Provided	Complied	
	8.	**3.2.P.8** Provide commercial invoice wherein Lot No IBP2210030 and quantity of API to be mentioned.	Commercial invoice dated 08.12.2022 is provided wherein Lot No IBP2211030 and quantity of API (3 KG)	Complied	
	9.	**3.2.P.8** Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month and onward (both accelerated and real time) to be provided.	Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month and onward (both accelerated and real time) is provided.	Complied	

Decision: Approved. Registration letter will be issued upon submission of following:

i. **Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.**
ii. **Suitability testing/quality testing (as per pharmacopeia) of container closure system (PET bottle).**

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
469.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying "Oral Liquid (General) section".
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16128 dated 28-06-2023
	Details of fee submitted	PKR 30,000/- dated 08/05/2023
	The proposed proprietary name / brand name	**Qad-fen 200mg/5ml suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension contains: Ibuprofen…..... 200mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Oral Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	90ml and 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Brufen 200mg/5ml by Mylan MHRA approved
	For generic drugs (me-too status)	Brufen 200mg/5ml by M/s Abbott Laboratories Pakistan Ltd. Reg No 070851
	Name and address of API manufacturer.	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months **Batches:** IBP1806001, IBP1806002, IBP1806003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the brand leader that is **Brufen 200mg/5ml suspension** by M/s Abbott Laboratories Pakistan (**Batch No 482476XY, Mfg date 01-2023)** performing quality tests (Identification, Assay, Dissolution, deliverable volume, pH, water content and Uniformity of dosage form). CDP has been performed against same product **Brufen 200mg/5ml suspension** by M/s Abbott Laboratories Pakistan in pH 1.2, pH 4.5 & Phosphate Buffer pH 6.8. The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur-55050 Punjab, Pakistan.
API Lot No..Batch number	IBP2210030
Description of Pack	

(Container closure system)	90ml and 120ml PET bottle amber colour in unit carton 1x1's		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LS013	LS014	LS015
Batch Size	50 bottles	50 bottles	50 bottles
Manufacturing Date	12/22	12/22	12/22
Date of Initiation	25-12-2022	25-12-2022	25-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of GMP certificate based on inspection dated 14-07-2016 issued by DRAP Pakistan
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*	
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / APImanufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has provided copy of GMP certificate based on inspection dated 03-03-2023 issued by DRAP Pakistan	Complied
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
4.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the	Analytical Method Verification studies of Drug substance performed by the Drug	Analytical Method Verification studies of Drug substance performed by the

		Drug Product manufacturer to be provided.	Substance manufacturer is submitted	Drug Product manufacture yet to be provided	
	5.	**3.2.P.2** Provide suitability testing/quality testing (as per pharmacopeia) of container closure system (PET bottle)	Not provided	Quality testing method is submitted as per USP however test result /performance report yet to be submitted.	
	6.	**3.2.P.5** Justify chromatographic conditions adopted in assay since chromatographic conditions mentioned in USP as: Detector: UV 254 nm. Flow rate: 1.0 mL/min While chromatographic conditions adopted by firm as: Detector: UV 220 nm Flow rate: 2 mL/min	Firm has provided reference of USP38-NF33 wherein chromatographic conditions mentioned were as follows: Detector: UV 220 nm Flow rate: 2 mL/min	chromatographic conditions to be adopted as per latest version of monograph USP 2023 as follows: Detector: UV 254 nm. Flow rate: 1.0 mL/min	
	7.	**3.2.P.8** Chromatograms of dissolution study has not been provided.	Provided	Complied	
	8.	**3.2.P.8** Provide commercial invoice wherein Lot No IBP2210030 and quantity of API to be mentioned.	Commercial invoice dated 08.12.2022 is provided wherein Lot No IBP2211030 and quantity of API (3 KG)	Complied	
	9.	**3.2.P.8** Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month and onward (both accelerated and real time) to be provided.	Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month and onward (both accelerated and real time) is provided.	Complied	

Decision: Approved. Registration letter will be issued upon submission of following:

i. **Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.**
ii. **Suitability testing/quality testing (as per pharmacopeia) of container closure system (PET bottle).**

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

470.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Capsule (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24302 dated 04-10-2023
	Details of fee submitted	PKR 30,000/- Dated 22/08/2023
	The proposed proprietary name / brand name	**Mebqad 200mg capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Sustained release pellets of Mebeverine HCl ……. 200mg
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	BP
	Proposed Pack size	1x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colofac 200mg Modified Release capsule Mylan MHRA approved
	For generic drugs (me-too status)	Mebever MR capsule M/s *Getz Pharma Pakistan* Ltd Reg No 050747
	Name and address of API manufacturer.	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months MBV-SR-028 MBV-SR-029 MBV-SR-030 The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36months. MBV-80-SR-001 MBV-80-SR-002 MBV-80-SR-003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Comparator product that is Mebever 200mg capsule (Batch No 187C31, Exp date 11/2025) of M/s *Getz Pharma Karachi* performing quality tests (Identification, Assay, Dissolution, LOD, Average weight and Uniformity of dosage form). CDP has been performed against the same brand that is Mebever 200mg capsule (Batch No 187C31) of M/s *Getz Pharma Karachi* in pH 1.2 (120min), & Phosphate Buffer pH 6.8 (up to 16 hours). The values for f1 and f2 are in the acceptable range.
	Analytical method validation study of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Surge Laboratories (Pvt) Ltd., 10 Km, Faisalabad road, Sheikhupura-Pakistan
API Lot No..Batch number	MBV-80-SR-066
Description of Pack (Container closure system)	Alu-Alu blister with unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CTR040	CTR041	CTR042
Batch Size	1000 cap	1000 cap	1000 cap
Manufacturing Date	01/23	01/23	01/23
Date of Initiation	16/01/23	17/01/23	17/01/23
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate dated 04.07.2019 issued by DRAP is provided. Based on inspection dated 03.07.2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of invoice (Invoice# 23010247-SG) dated 06-01-2023, with received quantity i.e. 2Kg) for the purchase of Mebeverine Pellets 80% (Batch No MBV-80-SR-066) from M/s Surge Laboratories, Pakistan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the **Mebeverine SR pellets** manufacturer issued by DRAP. Moreover, approval for manufacturing **Mebeverine SR pellets** to be mentioned.
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	**3.2.S.4** Justify acceptance criteria/ selection of chromatographic parameters including wavelength since 263nm is mentioned in BP for tablet dosage form while pellet manufacturer adjusted wavelength at 216nm. Moreover acceptance criteria for assay is mentioned as 95-105% in BP while firm adopted 90-110% .
5.	**3.2.P.2** The excipients used by pellet manufacturer such as Eudragit, Triethylcitrate and acetone have not been found in innovator/reference product. Drug-excipients compatibility study is required. Moreover, excipients such as Magnesium stearate polyacrylate dispersion 30%, hypromellose, methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30%, glycerol triacetate have been used in reference product (Colofac MR capsule) but not found in applied formulation. Clarify implication of not using said ingredients.
6.	**3.2.P.5** Finished product specification mentioned on Form5F as BP while specifications mentioned under section 3.2.P.5 as USP 43. However, modified release capsule of Mebeverine are not found in any official monograph. Provide correct reference of finished product specification accordingly.

	7.	**3.2.P.5** The specification includes tests for appearance, identity, average fill weight, uniformity of fill weight, uniformity of dosage units, water content, dissolution, related substances, assay, residual solvents and microbial quality https://www.geneesmiddeleninformatiebank.nl/pars/h123532.pdf Tests like uniformity of fill weight, uniformity of dosage units, water content, residual solvents and microbial quality has not performed by finished product manufacturer	

Reply:

Sr.#	Observations
1.	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet.*
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the **Mebeverine SR pellets** manufacturer based on inspection dated 25.08.2022 issued by DRAP (valid till 2 years) wherein approval for manufacturing **Mebeverine SR pellets** has been mentioned.
3.	Batch Manufacturing Record (BMR) for manufacturing all 3 batches of drug product has been provided.
4.	Analytical method has been revised as per BP 2023 wherein acceptance criteria of assay and chromatographic conditions have been mentioned as per BP. (90-110% and 263nm).
5.	Drug-excipients compatibility study has been provided (binary method). There is no significant change occurs during compatibility study.
6.	*Finished product specification mentioned on Form5F as BP because* **Mebeverine SR *capsule*** *is available in official monograph of BP 2023. while specifications mentioned under section 3.2.P.5 as USP 43 is writing mistake.*
7.	Tests like uniformity of fill weight and water content, have been performed by finished product manufacturer. Morever quality tests will be performed as per BP 2023

Decision: Approved.

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

471.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Tablet (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24685 dated 10-10-2023
	Details of fee submitted	PKR 30,000/- Dated 15/09/2023
	The proposed proprietary name / brand name	**Rostat 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin Calcium eq to Rosuvastatin.....5mg
	Pharmacotherapeutic Group of (API)	Hypolipidemic agent, Statin
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	10's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Crestor tablet by Astrazeneca, UK
	For generic drugs (me-too status)	Rovista tablet by M/s Getz pharmaceutical Reg No 044043
	Name and address of API manufacturer.	M/s Sumar Biotech LLP Plot No 112,113,114 GIDC Estate Gozaria, Tal and Dist Mehsana 382 825, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	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. SBL/SRD/ROS/19/19/036, SBL/SRD/ROS/19/19/037 SBL/SRD/ROS/19/19/038 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time

		stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures,validation of analytical procedures, batch analysis,justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Rovista 5mg tablet** by **Getz Pharma, Karachi.** Quality parameters such as appearance, average weight, disintegration time, dissolution content uniformity and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Rovista 5mg tablet (Batch No F05016, Exp date 05/26)** by **Getz Pharma, Karachi** in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Citrate Buffer (pH 6.6). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sumar Biotech LLP Plot No 112,113,114 GIDC Estate Gozaria, Tal and Dist Mehsana 382 825, Gujrat, India.		
API Lot No..Batch number	SBL/SRD/ROS/19/19/045		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR028	TTR029	TTR030
Batch Size	400 tab	400 tab	400 tab
Manufacturing Date	02/23	02/23	02/23
Date of Initiation	06/02/23	06/02/23	06/02/23
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No S-GMP&GLP/22103626 issued by Food and Drug Control Administration. The certificate is valid till 17 October 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# PI/030/22-23 dated 20-12-2022, with received quantity i.e. 200g) for the purchase of Rosuvastatin calcium USP (Batch No SBL/SRD/ROS/19/19/045) from M/s Sumar Biotech LLP Gujrat, India.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet*.	
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the 3 stability batches of drug product has been provided	Complied
3.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer to be provided.	Analytical Method Verification studies of Drug substance from Drug substance manufacturer is submitted	Analytical Method Verification studies from Drug Product manufacturer is required.
4.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.	Certificate of primary standard (USP) is provided (USP Lot No R148P0)	Complied
5.	**3.2.S.7** Submit real time stability data conducted as per Zone IV-A conditions i.e. 30°C ± 2°C / 65% ± 5% RH.	Real time stability data conducted as per Zone IV-A conditions i.e. 30°C ± 2°C / 65% ± 5% RH for 24 months. Batches: SBL/SRD/ROS/19/19/036 SBL/SRD/ROS/19/19/037 SBL/SRD/ROS/19/19/038	Complied

	6.	**3.2.P.2.2.1** Provide rationale for using citrate buffer instead of Phosphate buffer (pH 6.8) under CDP.	Dissolution/CDP was performed using Citrate buffer (pH 6.6) as mentioned in USP monograph (2023)	Justified.	
	7.	**3.2.P.8** Documents for the procurement of API, cleared by I&E, DRAP to be submitted	Provided copy of commercial invoice (Invoice# PI/030/22-23 dated 20-12-2022, with received quantity i.e. 200g) for the purchase of Rosuvastatin calcium USP (Batch No SBL/SRD/ROS/19/19/045) from M/s Sumar Biotech LLP Gujrat, India. Cleared by DRAP (I&E) Lahore dated 30 Jan 2023	Complied	

Decision: Approved. Registration letter will be issued after submission of Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.

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

472.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Tablet (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23865 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 15/09/2023
	The proposed proprietary name / brand name	**Rostat 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin Calcium eq to Rosuvastatin..... 10mg

	Pharmacotherapeutic Group of (API)	Hypolipidemic agent, Statin
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	10's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Crestor tablet by Astrazeneca, UK
	For generic drugs (me-too status)	Rovista tablet by M/s Getz pharmaceutical Reg No 044044
	Name and address of API manufacturer.	M/s Sumar Biotech LLP Plot No 112,113,114 GIDC Estate Gozaria, Tal and Dist Mehsana 382 825, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	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. SBL/SRD/ROS/19/19/036, SBL/SRD/ROS/19/19/037 SBL/SRD/ROS/19/19/038 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,justification of specifications, reference standard or materials, container closure system and

		stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Rovista 10mg tablet** by **Getz Pharma, Karachi.** Quality parameters such as appearance, average weight, disintegration time, dissolution content uniformity and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Rovista 10mg tablet (Batch No F06038, Exp date 04/26)** by **Getz Pharma, Karachi** in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Citrate Buffer (pH 6.6). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sumar Biotech LLP Plot No 112,113,114 GIDC Estate Gozaria, Tal and Dist Mehsana 382 825, Gujrat, India.		
API Lot No..Batch number	SBL/SRD/ROS/19/19/045		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR031	TTR032	TTR033
Batch Size	400 tab	400 tab	400 tab
Manufacturing Date	02/23	02/23	02/23
Date of Initiation	06/02/23	06/02/23	06/02/23
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No S-GMP&GLP/22103626 issued by Food and Drug Control Administration. The certificate is valid till 17 October 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# PI/030/22-23 dated 20-12-2022, with received quantity i.e. 200g) for the purchase of Rosuvastatin calcium USP (Batch No SBL/SRD/ROS/19/19/045) from M/s Sumar Biotech LLP Gujrat, India.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet*.	
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the 3 stability batches of drug product has been provided	Complied
3.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer to be provided.	Analytical Method Verification studies of Drug substance from Drug substance manufacturer is submitted	Analytical Method Verification studies from Drug Product manufacturer is required.
4.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.	Certificate of primary standard (USP) is provided (USP Lot No R148P0)	Complied
5.	**3.2.S.7** Submit real time stability data conducted as per Zone IV-A conditions i.e. 30°C ± 2°C / 65% ± 5% RH.	Real time stability data conducted as per Zone IV-A conditions i.e. 30°C ± 2°C / 65% ± 5% RH for 24 months. Batches: SBL/SRD/ROS/19/19/036 SBL/SRD/ROS/19/19/037 SBL/SRD/ROS/19/19/038	Complied
6.	**3.2.P.2.2.1** Provide rationale for using citrate buffer instead of Phosphate buffer (pH 6.8) under CDP.	Dissolution/CDP was performed using Citrate buffer (pH 6.6) as mentioned in USP monograph (2023)	Justified.
7.	**3.2.P.8** Documents for the procurement of API, cleared by I&E, DRAP to be submitted	Provided copy of commercial invoice (Invoice# PI/030/22-23 dated 20-12-2022, with received quantity i.e. 200g) for the purchase of Rosuvastatin calcium USP (Batch No SBL/SRD/ROS/19/19/045) from M/s Sumar Biotech LLP Gujrat, India. Cleared by DRAP (I&E)	Complied

			Lahore dated 30 Jan 2023		

Decision: Approved. Registration letter will be issued after submission of Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.

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

473.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.**
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot**.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not provided
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 17-09-2021 specifying Tablet (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23866 dated 28-09-2023
	Details of fee submitted	PKR 30,000/- Dated 15/09/2023
	The proposed proprietary name / brand name	**Rostat 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin Calcium eq to Rosuvastatin.....20mg
	Pharmacotherapeutic Group of (API)	Hypolipidemic agent, Statin
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Crestor tablet by Astrazeneca, UK
	For generic drugs (me-too status)	Rovista tablet by M/s Getz pharmaceutical Reg No 044044
	Name and address of API manufacturer.	M/s Sumar Biotech LLP Plot No 112,113,114 GIDC Estate Gozaria, Tal and Dist Mehsana 382 825, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	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. SBL/SRD/ROS/19/19/036, SBL/SRD/ROS/19/19/037 SBL/SRD/ROS/19/19/038 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Rovista 20mg tablet** by **Getz Pharma, Karachi.** Quality parameters such as appearance, average weight, disintegration time, dissolution content uniformity and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Rovista 20mg tablet (Batch No F07020, Exp date 04/26)** by **Getz Pharma, Karachi** in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Citrate Buffer (pH 6.6). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Sumar Biotech LLP Plot No 112,113,114 GIDC Estate Gozaria, Tal and Dist Mehsana 382 825, Gujrat, India.		
API Lot No..Batch number	SBL/SRD/ROS/19/19/045		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR034	TTR035	TTR036
Batch Size	400 tab	400 tab	400 tab
Manufacturing Date	02/23	02/23	02/23
Date of Initiation	06/02/23	06/02/23	06/02/23
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No S-GMP&GLP/22103626 issued by Food and Drug Control Administration. The certificate is valid till 17 October 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# PI/030/22-23 dated 20-12-2022, with received quantity i.e. 200g) for the purchase of Rosuvastatin calcium USP (Batch No SBL/SRD/ROS/19/19/045) from M/s Sumar Biotech LLP Gujrat, India.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide updated GMP status of finished product manufacturer	*New DML was granted dated 17-09-2021, we are in the process of product registration so we have not applied for GMP yet*.	
2.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the 3 stability batches of drug product has been provided	Complied

	3.	**3.2.S.4** Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer to be provided.	Analytical Method Verification studies of Drug substance from Drug substance manufacturer is submitted	Analytical Method Verification studies from Drug Product manufacturer is required.	
	4.	**3.2.S.5** COA of primary / secondary reference standard including source and lot number to be provided.	Certificate of primary standard (USP) is provided (USP Lot No R148P0)	Complied	
	5.	**3.2.S.7** Submit real time stability data conducted as per Zone IV-A conditions i.e. 30°C ± 2°C / 65% ± 5% RH.	Real time stability data conducted as per Zone IV-A conditions i.e. 30°C ± 2°C / 65% ± 5% RH for 24 months. Batches: SBL/SRD/ROS/19/19/036 SBL/SRD/ROS/19/19/037 SBL/SRD/ROS/19/19/038	Complied	
	6.	**3.2.P.2.2.1** Provide rationale for using citrate buffer instead of Phosphate buffer (pH 6.8) under CDP.	Dissolution/CDP was performed using Citrate buffer (pH 6.6) as mentioned in USP monograph (2023)	Justified.	
	7.	**3.2.P.8** Documents for the procurement of API, cleared by I&E, DRAP to be submitted	Provided copy of commercial invoice (Invoice# PI/030/22-23 dated 20-12-2022, with received quantity i.e. 200g) for the purchase of Rosuvastatin calcium USP (Batch No SBL/SRD/ROS/19/19/045) from M/s Sumar Biotech LLP Gujrat, India. Cleared by DRAP (I&E) Lahore dated 30 Jan 2023	Complied	

Decision: Approved. Registration letter will be issued after submission of Analytical Method Verification studies of Drug substance performed by the Drug Product manufacturer.

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

b) M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura

CLB in its 285th meeting held on 17th and 18th March, 2022 has considered and approved the grant of DML by way of Formulation with following 3 sections:

- Tablet (General)
- Capsule Section (General)
- Oral Dry powder suspension (General)
- Sachet (General)

474.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura**
	Name, address of Manufacturing site.	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License DML granted on 09.04.2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 19872 dated 10-08-2023
	Details of fee submitted	PKR 30,000/- Dated 09/08/2023
	The proposed proprietary name / brand name	**Leofold 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Levofloxacin Hemihydrate eq. to Levofloxacin 250mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone Antibiotic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's, 2x10's 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Leflox 250mg Tablet of M/s Getz Pharma (Pvt.) Limited Karachi (Reg. No. 026164)
	For generic drugs (me-too status)	Leflox 250mg film coated tablet USFDA approved
	Name and address of API manufacturer.	Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd. 333, Jiangnan Road, Hengdian, Dongyang, Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	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. DC-0401-1203001 DC-0401-1203002 DC-0401-1203003 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Leflox 250mg Tablet** manufactured by Getz Pharma Pvt. Ltd (Batch No F01039, Exp date 11/2025) Quality parameters such as appearance, average weight, disintegration time, dissolution, weight variation, uniformity of dosage and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Leflox 250mg Tablet** manufactured by Getz Pharma Pvt. Ltd (Batch No F01039, Exp date 11/2025) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for both drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd. 333, Jiangnan Road, Hengdian, Dongyang, Zhejiang China.		
API Lot No..Batch number	KY-LFA-M20220203E		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TT025	TT026	TTR027
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	09/22	09/22	09/22
Date of Initiation	29/09/22	29/09/22	29/09/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No ZJ20190145 issued by National Medical Product Administration dated 30.11.2019. The certificate is valid till 29 November 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has loan agreement for borrowing API from M/s Demont Research Lab as intimated by firm dated 15.02.2023. Provided copy of clearance certificate dated 01-08-2022, with received quantity i.e. 100Kg) of Levofloxacin hemihydrate USP (Batch No KY-LFA-M20220203E) from M/s Zhejiang Apeloa Kangyu Pharmaceutical China.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Decision: Approved.

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

475.	**Name, address of Applicant / Marketing**	**M/s ICU Pharmaceuticals, Khewat No.**

	Authorization Holder	**13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura**
	Name, address of Manufacturing site.	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License DML granted on 09.04.2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 19873 dated 10-08-2023
	Details of fee submitted	PKR 30,000/- Dated 09/08/2023
	The proposed proprietary name / brand name	**Leofold 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Levofloxacin Hemihydrate Eq. to Levofloxacin 500mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone Antibiotic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's, 2x10's 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Leflox 500mg Tablet of M/s Getz Pharma (Pvt.) Limited Karachi (Reg. No. 026163)
	For generic drugs (me-too status)	Leflox 500mg film coated tablet USFDA approved
	Name and address of API manufacturer.	Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd. 333, Jiangnan Road, Hengdian, Dongyang, Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	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. DC-0401-1203001 DC-0401-1203002 DC-0401-1203003 The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Leflox 500mg Tablet** manufactured by Getz Pharma Pvt. Ltd (Batch No F02051, Exp date 11/2025) Quality parameters such as appearance, average weight, disintegration time, dissolution, weight variation, uniformity of dosage and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Leflox 500mg Tablet** manufactured by Getz Pharma Pvt. Ltd (Batch No F02051, Exp date 11/2025) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for both drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd. 333, Jiangnan Road, Hengdian, Dongyang, Zhejiang China.
API Lot No..Batch number	KY-LFA-M20220203E

Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TT028	TT029	TTR030
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	09/22	09/22	09/22
Date of Initiation	29/09/22	29/09/22	29/09/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No ZJ20190145 issued by National Medical Product Administration dated 30.11.2019. The certificate is valid till 29 November 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has loan agreement for borrowing API from M/s Demont Research Lab as intimated by firm dated 15.02.2023. Provided copy of clearance certificate dated 01-08-2022, with received quantity i.e. 100Kg) of Levofloxacin hemihydrate USP (Batch No KY-LFA-M20220203E) from M/s Zhejiang Apeloa Kangyu Pharmaceutical China.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Decision: Approved.

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

476.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura**
	Name, address of Manufacturing site.	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License DML granted on 09.04.2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25450 dated 20-10-2023
	Details of fee submitted	PKR 30,000/- Dated 11/10/2023
	The proposed proprietary name / brand name	**Macedol Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Paracetamol..... 325mg Tramadol HCl 37.5mg
	Pharmacotherapeutic Group of (API)	Analgesic/ Opioid Analgesic
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's, 2x10's, 3x10's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tramadol 37.5/paracetamol 325 tablet MHRA approved
	For generic drugs (me-too status)	Tonoflex-P Tablet of M/s SAMI Pharma (Pvt.) Limited Karachi (Reg. No. 067163)
	Name and address of API manufacturer.	**For Paracetamol** **Pharmagen Limited** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore **For Tramadol HCl** **Aurobindo Pharma Limited,** On M/s. SLR Pharma Private Limited Plot No: A-69 , API Estate, Settipalli (Post), Tirupati-517506, Chittoor (dist.), Andhra Pradesh, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both drug substances at both accelerated as well as real time conditions. **Paracetamol:** The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. LE/001/2016 LE/002/2016 LE/003/2016 The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. LE00510911/001/2016 LE00510911/002/2016 LE00510911/003/2016 **Tramadol:** The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. TDH0010211 TDH0020211 TDH0010211
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against **Tonoflex P Tablet** manufactured by **Sami Pharma** (Batch No 032K, Exp date 03/2025) Quality parameters such as appearance, average weight, disintegration time, dissolution, uniformity of dosage and assay against Test product. Firm has submitted CDP results of their product against the same comparator product **Tonoflex P Tablet** manufactured by **Sami Pharma** (Batch No

		032K, Exp date 03/2025) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for both drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	**For Paracetamol** **Pharmagen Limited** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore **For Tramadol HCl** **Aurobindo Pharma Limited,** On M/s. SLR Pharma Private Limited Plot No: A-69 , API Estate, Settipalli (Post), Tirupati-517506, Chittoor (dist.), Andhra Pradesh, INDIA.		
API Lot No..Batch number	Paracetamol: 00510911/184/2022 Tramadol HCl: APL0050222		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TT031	TT032	TT033
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	11/22	11/22	11/22
Date of Initiation	23/11/22	23/11/22	23/11/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** Firm has submitted copy of GMP certificate dated 22.11.2022 issued by DRAP based on inspection dated 18.11.2022. The certificate is valid till two years. **Tramadol:** Firm has submitted copy of GMP certificate No. L.Dis. No. HMF07-12041-7-2023-ACC-DCA dated 28.06.2023 issued by DCA Andhra Pradesh valid till 27-06-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has loan agreement for borrowing API from M/s Demont Research Lab as intimated by firm dated 15.02.2023. **For Tramadol HCl** Provided copy of clearance certificate dated 14-06-2022, with received quantity i.e. 100Kg)

		of Tramadol HCl USP (Batch No APL0050222) from M/s Aurobindo Pharma Limited. India **For Paracetamol** Provided copy of delivery note (No 1895) dated 09-08-2022, with received quantity i.e. 1.5 Kg) of Paracetamol (Batch No 00510911/184/2022) from M/s Pharmagen Limited. Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Deferred cases:

477.	Name, address of Applicant / Marketing Authorization Holder	M/s Nawan Laboratories Ltd. 136, sector 15, KIA, Korangi Karachi from M/s Bio-Labs (Pvt) Ltd
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8005 dated 11-03-2021
	Details of fee submitted	PKR 50,000/- (#2009144) dated 17-02-2021
	The proposed proprietary name / brand name	Nevitix Injection 500mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Mecobalamin ……. 500mcg
	Pharmaceutical form of applied drug	Almost red colour solution filled in amber glass ampoule.
	Pharmacotherapeutic Group of (API)	Antianemia
	Reference to Finished product specifications	Innovator's

	Proposed Pack size	1ml x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methycobal Injection PMDA approved
	For generic drugs (me-too status)	Amcobal Injection 500mcg/ml by Amson Vaccine & Pharma 069899
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conduct 23-4-2019, valid upto 22-4-2022.
	Name and address of API manufacturer.	M/s. Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. (assay by HPLC with PDA detector, limit 98to 101%), residual solvent by GC
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 ^{O} ± 2 ^{O} C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2 ^{O} C / 65% ± 5% RH for 48 months (batch no. 7805016001, 7805016002 & 7805016003).
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Methycobal 500 mg injection by Hilton Pharma
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India		
API Lot No.	MCB2010061		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	A-431	A-443	A-456
Batch Size	37,000 Ampoules	10,000 Ampoules	10,800 ampoules
Manufacturing Date	04-2018	05-2018	06-2018
Date of Initiation	29-8-2018	2-7-2018	10-09-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate # 20031928 of M/s. Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India valid upto 16-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted attested copy of invoice (invoice # HHM/2021/00256) attested by AD DRAP
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator [VII]:

Sr. No.	Section #.	Deficiencies	Reply
1.	***3.2.P.2***	How much overage is added in the formulation? Justify the percentage of overage added in the formulation	30% overage is added
2.	***3.2.P.8***	Justify the selection of limit of assay test as "90 – 150 %" while	For the case of Vitamin preparations normally and

			the official limit of vitamin preparations is 120%.	most of the cases followed Compendial limits are 90-130%. In our nivitex inj 500mcg we have added 30% of overage in the batch formula. Unit contains 30% of overage of API, So considering the addition of 30% of overage, assay limits are set as 90-150%. We have now revised the specs and make it more stringent after complete stability data and market feedback, so the revised limits are now set as 90-130%.	
	3.	***3.2.P.8***	Justify how UV method was adopted for the testing of drug product, since the testing method of drug substance manufacturer for assay of mecobalamin was based on HPLC	M/s Bio-labs have the registration of our product Mine injection as per manufacture specification and UV-VIS Spectrophotometer method is DRAP approved method. Since stability data is proved at old batches of 2018 so the applied method is UV-VIS Spectrophotometer which has been updated now. Validation of the applied testing method has been provided in terms of all the parameters as per validation guidelines.	
	4.	***3.2.P.8***	Justify the effective date on stability data sheet is 01-01-2020 but the stability starts at 29-08-2018	Effective data on stability data sheet is 01-01-2020 because old data has been provided on the new formats. Formats for interpretations of stability results are new and revised with old stability data for presentation.	
	5.	***3.2.P.8***	Justify the results of assay as all the batches just showed minor decrease in assay results less than which is usually observed in vitamin preparations. Scientific justification / clarification is required in this regard.	Results of assay showed normal decrease in assay results, which is well withinthe trend as of vitamins preparation. In the stabilitydata provided, assay results decrease gradually e.g. in batch number A-431 assay results decreases from 122…62% to 109-93% (stability sheet for real time analysis provided), in batch number A-433 assay results decreased from 121.21% to 107-23% and in batch number A-456 results	

				decreased from 121.2% to 106-83%.	

Decision of 316: Deferred for the following
Justify how UV method was adopted for the testing of drug product, since the testing method of drug substance manufacturer for assay of mecobalamin was based on HPLC
Justification for the results of assay
Justification of the percentage of overage added in the formulation

Remarks of evaluator PEC [VII]

S. No.	Deficiency in 316th Meeting	Documents Attached
1.	Deferred for: • Justification of applying UV Spectrophotometric method for the assay test of drug product, since the testing method of drug substance manufacturer for assay of mecobalamin was based on HPLC.	Bio-Labs has registration of mecobalamine injection as per manufacturer specifications. Since stability data has been provided of old batches so applied testing method along with method validation was submitted. However, the testing method of the mecobalamine injection has been updated to HPLC. The method validation of the new method is attached herewith. Both the methods (UV-spectrophotometric and HPLC) are validated in all aspects of ICH guidelines.
	• Justification for declining trend of assay results.	As the mecobalamin is light sensitive product and gradually degrades with the time, due to this reason there is declining trend in the analysis of assay. In order to achieve patient compliance and provision of complete dose, overage has been added so that the contents of API remain within claim limit during product shelf life.
	• Justification of the percentage of overage added in the formulation.	As the mecobalamine is light sensitive product and gradually degrades with the time, due to this reason there is declining trend in the analysis of assay. In order to achieve patient compliance and provision of complete dose, overage has been added so that the contents of API remain within claim limit during product shelf life.

Decision 321st meeting : Registration Board noted the fact that the %age overage used in the applied formulation was above the general permissible limits of overage hence the Board deferred the case for submission of new 6 month stability studies data of drug product at accelerated and long term conditions of Zone IVA, with revised formulation excluding overage, drug product specifications and drug product analytical procedure based upon HPLC Assay method.

Updated status:

- Batch formula is provided wherein no overage is mentioned however quantity of API will be adjusted as per assay of actual lot used in manufacturing.
- Firm has submitted finished product specifications with assay limit 95-115%
- Analytical testing method is submitted wherein assay will be performed by HPLC method
- Trial batches manufacturing record is provided.

- Stability data is submitted as follows**:**

Batch No	A-018	A-019	A-020
Batch size	1000 Ampoules	1000 Ampoules	1000 ampoules
Mfg date	04-2023	04-2023	04-2023
Exp date	03-2025	03-2025	02-2025
Date of initiation of stability study	05.04.2023		
API lot No	M210909A		

Shortcomings:

- Since API Lot used in formulation development and stability studies have been changed hence CoA of relevant lot No (M210909A) to be provided from both Drug substance as well as Drug product manufacturer.
- Documents for procurement of relevant batch of API, approved by I&E DRAP to be submitted**.**

Decision: Approved.

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

478.	Name, address of Applicant / Marketing Authorization Holder	M/s OPHTH PHARMA (PVT.) LTD. Plot No. 241, Sector-24, Korangi Industrial Area, Karachi-Pakistan
	Name, address of Manufacturing site.	M/s OPHTH PHARMA (PVT.) LTD. Plot No. 241, Sector-24, Korangi Industrial Area, Karachi-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of DML renewal inspection report dated 27-09-2021 wherein it was concluded to be GMP compliant.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML renewal inspection report dated 27-09-2021 specifying Ophthalmic ointment/cream section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8514 dated 01/04/2022
	Details of fee submitted	PKR 30,000/- dated 03/02/2022
	The proposed proprietary name / brand name	**FLUCOVET CREAM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Fluticasone Propionate … 0.5mg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Pharmaceutical form of applied drug	Topical cream

	Reference to Finished product specifications	USP specification
	Proposed Pack size	15gm
	Proposed unit price	Not mentioned
	The status in reference regulatory authorities	Fluticasone Propionate Cream Fougera Pharms USA USFDA approved
	For generic drugs (me-too status)	Cutivate Cream GSK Reg No 058448
	Name and address of API manufacturer.	FARMABIOS Via Pavia, 1 27027 Gropello Cairoli(PV) Italy
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 months. Batches No : 0010715, 0010730, 0021008 (accelerated), 0010830 (real time)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not provided
	Analytical method validation/verification of product	Method verification studies have been submitted including accuracy and precision
STABILITY STUDY DATA		
Manufacturer of API	FARMABIOS	

	Via Pavia, 1 27027 Gropello Cairoli(PV) Italy		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Aluminium tube (15g)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	TB-101	TB-102	TB-103
Batch Size			
Manufacturing Date	January 2019	January 2019	January 2019
Date of Initiation	04.01.2019	04.01.2019	04.01.2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Assessor:

S.No	Observations
1.	Whether applied formulation is dermatologic or ophthalmic preparation since reference product/generic version is not meant for ophthalmic use. While firm intends to manufacture applied formulation in Ophthalmic ointment/cream section. Clarify the intended use.
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.
3.	2.3.S.5 COA of primary / secondary reference standard including source and lot number to be provided
4.	3.2.S.4 Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer to be provided
5.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.
6.	3.2.S.4 Provide certificate of analysis of relevant batch(es) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.

7.	3.2.S.4: Assay limit of drug substance is different from USP (98-100.5% instead of 90-101%) clarify it.	
8.	3.2.P.2 Provide Drug excipients compatibility study report for stearic acid, Polysorbate 80, glyceryl mono stearate, and Benzyl alcohol, being qualitatively different from innovator product.	
9.	3.2.P.2.2.1 Provide Pharmaceutical Equivalence against reference/comparator product wherein all quality parameters (as per USP) should be compared. Also provide image/snapshot/picture of Innovator Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	
10.	3.2.P.5: Assay limit is different from USP (90-115% instead of 90-110%) clarify it Moreover, microbial enumeration test has not been performed as per USP	
11.	3.2.P.5 Analytical testing method is different from USP method.	
12.	3.2.P.5 Analytical Method Verification studies of Drug Product including specificity (against sample, standard, placebo and blank) performed by the Drug Product manufacturer to be provided	
13.	3.2.P.8 Documents for the procurement of API, cleared by I&E, DRAP.	
14.	3.2.P.8 Microbial enumeration test and Ph have not been performed during stability studies.	
15.	3.2.P.8 Data of Accelerated stability study has not been provided. Moreover CoA at each time point and Batch size of stability batches to be provided.	
16.	3.2.P.8 Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	
17.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	

Decision 331st meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply:

S.No	Observations	Reply	Remarks
1.	Whether applied formulation is dermatologic or ophthalmic preparation since reference product/generic versionis not meant for ophthalmic use. While firm intends to manufacture applied formulation in Ophthalmic ointment/cream section. Clarify the intended use.	Firm clarified that applied formulation is "topical cream"	Manufacturing facility/section for "topical cream" to be provided. Since already provided evidence for section approval specified "Ophthalmic ointment/cream section"
2.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	GMP certificate (No IT-API/167/H/2022) based on inspection dated 01/10/2021 issued by AIFA, provided valid till three years from the date of inspection.	Complied
3.	2.3.S.5 COA of primary / secondary reference standard including source and lot number to be provided	Provided	Complied
4.	3.2.S.4 Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer to be provided	Provided	Complied

5.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Provided	Chromatographic conditions mentioned in USP under assay as: Injection volume:50UL Flow rate: 1.0 mL/min While chromatographic conditions adopted by firm as: Injection volume:20UL Flow rate: 1.5 mL/min Need to be justified.
6.	3.2.S.4 Provide certificate of analysis of relevant batch(es) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.	CoA from Finished product manufacturer is provided for lot No R-1506 while CoA from Drug substance manufacturer is provided for Lot No FP21406	CoA of relevant batch is required from both Drug Substance and Drug Product manufacturer.
7.	3.2.S.4: Assay limit of drug substance is different from USP (98-100.5% instead of 90-101%) clarify it.	Assay limit of drug substance is 98-102% as per USP as provided in analytical method and CoA.	Verified
8.	3.2.P.2 Provide Drug excipients compatibility study report for stearic acid, Polysorbate 80, glyceryl mono stearate, and Benzyl alcohol, being qualitatively different from innovator product.	Drug excipients compatibility study report (binary study) is provided wherein all excipients used were found compatible with API	Complied
9.	3.2.P.2.2.1 Provide Pharmaceutical Equivalence against reference/comparator product whereinall quality parameters (as per USP) should be compared. Also provide image/snapshot/picture of Innovator Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Pharmaceutical Equivalence study was performed against **Fluticasone Propionate Cream by Fougera Pharms USA** (Batch No RTY568, Exp date 10/2020) Quality parameters studied are appearance, identification, Ph, fill weight, assay and microbial enumeration test.	Complied
10.	3.2.P.5: Assay limit is different from USP (90-115% instead of 90-110%) clarify it Moreover, microbial enumeration test has not been performed as per USP	The Assay limit of product is as per USP monograph i.e 90-110%, assay limit 90-115% was mentioned mistakenly. The Assay	

		limit mentioned in stability section (3.2.P.8) is also 90-110%	
11.	3.2.P.5 Analytical testing method is different from USP method.	Analytical testing method of Drug product is submitted as per USP	Complied
12.	3.2.P.5 Analytical Method Verification studies of Drug Product including specificity (against sample, standard, placebo and blank) performed by the Drug Product manufacturer to be provided	Provided	Complied
13.	3.2.P.8 Documents for the procurement of API, cleared by I&E, DRAP.	Good receiving note dated 27.11.2018 is provided wherein 11.8 Kg fluticasone propionate received from FARMABIOS Italy has been mentioned	Commercial invoice and approval from I&E DRAP to be provided
14.	3.2.P.8 Microbial enumeration test and Ph have not been performed during stability studies.	Microbial enumeration test and Ph tests results are provided in stability data sheet	Complied
15.	3.2.P.8 Data of Accelerated stability study has not been provided. Moreover CoA at each time point and Batch size of stability batches to be provided.	Data of Accelerated stability study has been provided against each time point Batch size provided as 7.5kg (500 units)	Complied
16.	3.2.P.8 Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Provided	Complied
17.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied

Remarks: Manufacturing facility/section of **"Sterile eye ointment/Topical cream"** has been found approved as mentioned in letter dated 07.06.2022 regarding DML renewal by CLB (286th meeting) issued by secretary CLB.

Decision: Deferred for submission of following:

- **Chromatographic conditions (injection volume and flow rate) in analytical method of Drug Substance is not as per USP. Clarify it.**
- **CoA of relevant batch of Drug Substance(s) used in product development from both Drug Substance and Drug Product manufacturer.**
- **Documents for the procurement of API, cleared by I&E, DRAP.**

- **Dry Powder Inhaler Capsule (General) section in place of Sachet (General)-New.**

479.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34288 dated 28.11.2022
	Details of fee submitted	PKR 30,000/- dated 10.11.2022
	The proposed proprietary name / brand name	**Combrain 200mcg + 6mcg capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rotacapsule contains: Budesonide…. .....200mcg Formoterol fumarate… 6mcg
	Pharmaceutical form of applied drug	Dry powder for inhalation
	Pharmacotherapeutic Group of (API)	Corticosteroid and Long acting β_2 adrenergic agonist.
	Reference to Finished product specifications	As per innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Symbicort turbohaler 200mcg + 6mcg inhalation powder MHRA approved
	For generic drugs (me-too status)	Venticort Rota capsule Macter International Reg. No. 081177
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 12.10.2022 valid for **three years.** New Section Approval granted on 20-09-2021 (Dry Powder inhaler capsule) .
	Name and address of API manufacturer.	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Formoterol fumarate dihydrate** The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A&F, unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Budesonide:** The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,L,D,K & unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Formoterol fumarate dihydrate** Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(FF-0071013 M, FF-0010514 and FF-0010515 M) **Budesonide:** Real time: 30°C ± 2°C / 75% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(BDS-0071216, BDS-0010415 and BDS-0020514)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence of Eye Drop dosage form is performed. Moreover comparator product is to be clarified.
	Analytical method validation/verification of product	Summary report of method validation studies submitted including accuracy, precision, linearity, robustness.
STABILITY STUDY DATA		

Manufacturer of API	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Not provided		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-27	T-28	T-29
Batch Size	500 Caps	500 Caps	500 Caps
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	28-11-2021	28-11-2021	28-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of GMP (No NEW-WHO-GMP/CERT/PD/75003/2018/11/25587 valid till dated 02.11.2021 License retention certificate No 25-PD/29 dated 22/01/2018 valid till 31/12/2022 issued by FDA (Maharashtra state)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor (DD PEC$^{XX)}$:

1) Label claim of RRA approved formulation (Symbicort® Turbohaler® 200 micrograms/6 micrograms/ powder for inhalation) is as follows:

Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 160 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation.

Each metered dose contains: budesonide 200 micrograms/inhalation and formoterol fumarate dihydrate 6 micrograms/inhalation.
Firm has not provided information regarding ***delivered dose***

2) **3.2.P.2** In reference product quantity of Lactose monohydrate used is 730microgram while in applied formulation the quantity of Lactose monohydrate used was 50mg. justify it

3) **3.2.P.2** In reference product Lactose monohydrate is the only excipient been used while firm used other excipients as well such as Talcum powder, Macragol 100, Povidone, Aerosil 200 . justify it, also provide Drug-Excepient compatibility studies of said excipients.
4) **3.2.P.2** The container closure system of reference product, is an inspiratory flow-driven, multidose powder inhaler containing metered doses which is made of different plastic materials, while the applied formulation is primarily pre-dispensed in unit dose hard capsules. Justification shall be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule.
5) **3.2.P.5** Specification of Dug Product did not include water content test which is critical quality parameters for DPI.
6) **3.2.P.2** Pharmaceutical equivalence study to be performed including all quality parameters, Moreover, name batch no and manufacturer of both Test product and Reference product to be provided.
7) **3.2.P.2** Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.
8) **3.2.P.2** Potency adjustment (salt factor) calculation was not provided for Formoterol fumarate dihydrate in Batch formula.
9) **3.2.P.2** Detailed Analytical testing method of Drug Product to be provided.
10) **3.2.P.2** Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device (name, model, manufacturer and shelf life) provided in pack.
11) **3.2.P.8** Documents for the procurement of API to be submitted.
12) **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.
13) **3.2.S.4** Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer
14) **3.2.S.4** Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.
15) **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
16) **3.2.S.4** CoA of Drug Substance Formoterol fumarate dihydrate particle size distribution test was not performed which is critical quality attribute in applied formulation i.e DPI.

Decision 326th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.
Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section

Reply:

Sr.#	Section	Observations	Reply	Remarks
1.		Label claim of RRA approved formulation (Symbicort® Turbohaler® 200 micrograms/6 micrograms/	Firm has provided content of active ingredients emitted	Delivered dose of both ingredients is different from

			powder for inhalation) is as follows: ***Each delivered dose (the dose that leaves the mouthpiece) contains:*** ***budesonide 160 micrograms/inhalation and formoterol fumarate*** ***dihydrate 4.5 micrograms/inhalation.*** ***Each metered dose contains: budesonide 200 micrograms/inhalation*** ***and formoterol fumarate dihydrate 6 micrograms/inhalation.*** Firm has not provided information regarding ***delivered dose***	from the mouthpiece of DPI as follows: ***Budesonide 155 micrograms/inhalation delivered*** ***Formoterol fumarate*** ***dihydrate 4.2 micrograms/inhalation delivered*** Firm also provided detail of sampling apparatus (for determining content of active ingredients emitted from mouth piece)	RRA approved formulation.	
	2.	**3.2.P.2**	In reference product quantity of Lactose monohydrate used is 730microgram while in applied formulation the quantity of Lactose monohydrate used was 50mg. justify it	Firm has submitted revised master formulation wherein quantity of Lactose monohydrate mentioned as 20mg	In reference product quantity of Lactose monohydrate used is 730microgram quantity mentioned yet to be justified	
	3.	**3.2.P.2**	In reference product Lactose monohydrate is the only excipient been used while firm used other excipients as well such as Talcum powder, Macragol 100, Povidone, Aerosil 200 . justify it, also provide Drug-Excipient compatibility studies of said excipients	*In the earlier provided formulation excipients other than lactose monohydrate have been mentioned mistakenly. Corrected formulation is provided complying with reference product*	Revised formulation as per reference product has been submitted which is qualitatively similar to reference product.	
	4.	**3.2.P.2**	The container closure system of reference product, is an inspiratory flow-driven, multidose powder inhaler containing metered doses which is made of different plastic materials, while the applied formulation is primarily pre-dispensed in unit dose hard capsules. Justification shall be submitted for pharmaceutical	*Applied formulation is hard gelatin capsule containing powder for inhalation along with revolizer for Administration. It contains a container closure system in which capsule is placed and inhaled from mouth piece by inspiration, this is in accordance to*	Justification yet to be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary	

			equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule.	*reference productwhich is inspiratory flow driven.*	container closure system, compatibility of applied formulation with the hard gelatin capsule.
	5.	**3.2.P.5**	Specification of Dug Product did not include water content test which is critical quality parameters for DPI.	Specification of Drug product has been submitted wherein water content test is included.	Quality tests such as uniformity of delivered dose and aerodynamic assessment of fine particles have not been performed
	6.	**3.2.P.2**	Pharmaceutical equivalence study to be performed including all quality parameters, Moreover, name batch no and manufacturer of both Test product and Reference product to be provided.	Pharmaceutical equivalence study has been performed against comparator product: **Combivair** 200mcg/6mcg capsule **B.No:** 230519 **Exp date**: 07/2023 Quality parameters compared included: Water content, content uniformity, assay	Quality tests such as uniformity of delivered dose, aerodynamic assessment of fine particles and microbial contamination have not been performed
	7.	**3.2.P.2**	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Provided	Complied
	8.	**3.2.P.2**	Potency adjustment (salt factor) calculation was not provided for Formoterol fumarate dihydrate in Batch formula	Potency adjustment/salt factor calculation for Formoterol fumarate dihydrate has been provided in batch formula.	Complied
	9.	**3.2.P.2**	Detailed Analytical testing method of Drug Product to be provided.	Not provided	Not complied
	10.	**3.2.P.2**	Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device (name, model,	Detail of container closure system is provided as follows: 10 rotacap /blister (aluminium foil)	

			manufacturer and shelf life) provided in pack.	**Inhalation device:** **Name:** WRLflo **Model:** WRL-00753 **Manufacturer:** Winbrain **Shelf life**: 5 years.	
	11.	**3.2.P.8**	Documents for the procurement of API to be submitted.	Firm has provided copy of commercial invoice dated 26.10.2021 wherein **Formoterol fumarate dihydrate** EP (5gm) Batch No. FF-0090821 and **Budesonide EP** Batch No BDS-0510921 is mentioned .Approved by DRAP (I&E) Peshawar dated 9-11-2021	Complied
	12.	**3.2.P.8**	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Record of Digital data logger for temperature and humidity monitoring is provided	
	13	**3.2.S.4**	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Analytical procedures for the testing of Formoterol fumarate dihydrate is submitted as per BP. Analytical procedures for the testing of Budesonide is submitted as per Ph.Eur	Complied
	14	**3.2.S.4**	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Certificate of Analysis (COA) of relevant batches of both Drug Substances have been provided by Drug Substance manufacturer **Formoterol fumarate dihydrate** Batch No. FF-0090821 and **Budesonide** Batch No BDS-0510921	Certificate of Analysis (COA) of relevant batches to be provided from Drug product manufacturer as well
	15	**3.2.S.4**	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Analytical Method Verification studies of Formoterol fumarate dihydrate and Budesonide has not been provided by Drug Product manufacturer	Not complied
	16	**3.2.S.4**	CoA of Drug Substance Formoterol fumarate dihydrate	CoA of Formoterol fumarate dihydrate is	Complied

			particle size distribution test was not performed which is critical quality attribute in applied formulation i.e DPI.	provided wherein particle size distribution test has been included.	

Also provide registration status of previously registered products for "Sachet (general) section

Decision: Registration Board deferred the application for following shortcomings;

- **Justify quantity of Lactose monohydrate i.e 20mg per unit dose (rotacap) with reference to RRA approved formulation wherein quantity of Lactose monohydrate is mentioned as 730microgram per delvered dose.**
- **Perform quality tests such as uniformity of delivered dose and aerodynamic assessment of fine particles under finished product specification as well as pharmaceutical equivalence study.**
- **Provide detailed Analytical testing method of Drug Product.**
- **Provide CoA of relevant batches of both Drug Substances used in product development from Drug Product manufacturer.**
- **Provide Analytical Method Verification studies of both drug substances by the Drug Product manufacturer.**

480.	Name, address of Applicant / Marketing Authorization Holder	M/s Roryan Pharmaceutical Industries (Pvt) Ltd. 85B, Industrial Estate, Hayatabad Peshawar.
	Name, address of Manufacturing site.	M/s Roryan Pharmaceutical Industries (Pvt) Ltd. 85B, Industrial Estate, Hayatabad Peshawar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of inspection report conducted on 13-01-2022 for renewal of DML. Wherein panel recommended grant of renewal of DML.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 26.01.2011 Wherein Tablet (Psychotropic) section was approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 20928 dated 26-07-2022
	Details of fee submitted	PKR 30,000/- Dated 15-02-2022
	The proposed proprietary name / brand name	Zolim 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Zolpidem Tartrate 10mg
	Pharmacotherapeutic Group of (API)	Sedative-Hypnotic agent
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP specification
	Proposed Pack size	2 x 10's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	MHRA approved By Bristol Laboratories Ltd
	For generic drugs (me-too status)	Zolp 10mg Tablet Adamjee Pharmaceutical Reg No 029523
	Name and address of API manufacturer.	Centaur Pharmaceutical Pvt Ltd Address: Plot No. 75, 76 &76/1, Chikhloli MIDC, Ambernath (W), Dist Thane-421 501. Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Accelerated study: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (1802510P, 1802511P & 1802512P). Long term study: 30°C ± 2°C / 75% ± 5%RH for 60 months Batches: (20112502P, 20112501P, & 201402501P).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Zolp 10 mg Tablets manufactured by Adamjee Pharmaceutical Pakistan Limited Quality Parameter compared were DT, Weight variation, hardness, Dissolution and assay. Firm has submitted CDP results of their product against the same comparator product Zolp 10 mg

		Tablet in 3 dissolution medias. (pH 1.2, pH 4.5, pH 6.8) The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity..

STABILITY STUDY DATA			
Manufacturer of API	Centaur Pharmaceutical Pvt Ltd Address: Plot No. 75, 76 &76/1, Chikhloli MIDC, Ambernath (W), Dist Thane-421 501. Maharashtra, India		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 9 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6,9 (Months)		
Batch No.	T001	T002	T003
Batch Size	10000 tablets	10000 tablets	10000 tablets
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	24-08-2021	27-08-2021	31-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. New-WHO-GMP/CERT/KD/85796/2019/11/29756) valid until 10-10-2022 issued by Food & Drugs Administration, Maharashtra, India
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted all documents related to stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor (DD PEC XX):

S.No	Observations

	1.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	
	2.	3.2.S.4 Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer to be provided	
	3.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	
	4.	3.2.S.4 Provide certificate of analysis of relevant batch(es) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.	
	5.	3.2.P.2.2.1 Provide justification for selection of comparator product i.e Zolp 10 mg Tablets manufactured by Adamjee Pharmaceutical Pakistan Limited instead of innovator product (Stilnox 10mg tablet by Snofi Aventis, TGA approved) Reg No 021111. Also provide image/snapshot/picture of Innovator Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	
	6.	3.2.P.5 Analytical Method Verification studies of Drug Product including specificity (against sample, standard, placebo and blank) performed by the Drug Product manufacturer to be provided	
	7.	3.2.P.8 Documents for the procurement of API, cleared by I&E, DRAP.	
	8.	3.2.P.8 Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	
	9.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	

Decision 331st meeting: Registration Board deferred the case for submission of reply to the above cited Shortcomings.

Reply:

S.No	Observations	Reply	Remarks
1.	Provide valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory	Firm has submitted copy of GMP Certificate (No. New-WHO-GMP/CERT/KD/85796/2019/11/29756) valid until **10-10-2022** issued by Food & Drugs Administration, Maharashtra, India	Valid copy of GMP certificate yet to be submitted.

		authority of country of origin to be provided.			
	2.	3.2.S.4 Analytical Method Verification studies of Drug Substance performed by the Drug Product manufacturer to be provided	Analytical Method Verification studies of Drug Substance by Drug Product manufacturer has been submitted	Complied	
	3.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Method used for analysis of API from Drug Product manufacturer has been submitted	Complied	
	4.	3.2.S.4 Provide certificate of analysis of relevant batch(es) of Drug Substance(s) used in product development by both Drug Substance and Drug Product manufacturer.	CoA of relevant batch (No 2102506P) has been provided by Drug substance manufacturer.	CoA of relevant batch (No 2102506P) yet to be provided by Drug Product manufacturer.	
	5.	3.2.P.2.2.1 Provide justification for selection of comparator product i.e Zolp 10 mg Tablets manufactured by Adamjee Pharmaceutical Pakistan Limited instead of innovator product (Stilnox 10mg tablet by Snofi Aventis, TGA approved) Reg No 021111. Also provide image/snapshot/picture of Innovator Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Zolp 10 mg Tablet manufactured by Adamjee Pharmaceutical Pakistan Limited was used as comparator product Batch No 62 Exp date 10/2023 Reason for selection of said brand was Zolp 10mg tablet was easily available while stilnox was not available in the market.		

	6.	3.2.P.5 Analytical Method Verification studies of Drug Product including specificity (against sample, standard, placebo and blank) performed by the Drug Product manufacturer to be provided	Analytical Method Verification studies of Drug Product including specificity (against sample, standard, placebo and blank) performed by the Drug Product manufacturer has been provided	Complied	
	7.	3.2.P.8 Documents for the procurement of API, cleared by I&E, DRAP.	Firm has provided copy of commercial invoice No cp/exp/c/182/21-22 dated 07/07/2021 wherein Zolpidem Tartrate BP Batch No 2102506P (0.340Kg) is mentioned. Approved by I&E DRAP, Peshawar dated 07.04.2021	Complied	
	8.	3.2.P.8 Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is provided.		
	9.	2.3.R.1.1 Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all 3 batches is provided.	Complied	

Decision: Approved. Registration letter will be issued upon submission of following:

i. **Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin.**
ii. **CoA of relevant batch (No 2102506P) of drug substance by Drug Product manufacturer.**

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

481.	Name, address of Applicant / Marketing Authorization Holder	Kaizen Pharmaceuticals (Pvt.) Ltd., E-127, E-128, E-129, North Western Zone, Port Qasim Authority, Karachi

	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., E-127, E-128, E-129, North Western Zone, Port Qasim Authority, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP inspection report dated 11-08-2020 wherein firm was GMP compliant.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-09-2012 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11607 dated 13.05.2022
	Details of fee submitted	PKR 75,000/- Dated 25-02-2022
	The proposed proprietary name / brand name	**Minodron 1mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Minodronic Acid hydrate…..1mg
	Pharmacotherapeutic Group of (API)	Third Generation nitrogen containing biphosphonate
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	10's, 20's and 30's (As per SRO)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Recalbon 1mg Tablet (PMDA Approved) By Ono pharmaceutical Co Ltd
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	PROCOS S.p.A. Via Matteotti, 249 28062 Cameri (NO) - ITALY
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No: 0000244247, 0000244249, 0000244250
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Recalbon 1mg Tablet manufactured by ono pharmaceutical Co., Ltd. Parameters such as physical appearance, Hardness, DT, assay, dissolution was compared. Firm has submitted CDP results of their product against the innovator's product Recalbon 1mg Tablet in in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range..
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	PROCOS S.p.A. Via Matteotti, 249 28062 Cameri (NO) - ITALY		
API Lot No.	0000300533 0000300522		
Description of Pack (Container closure system)	Alu-PVC blister packing		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 18 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	05-2020	08-2020	08-2020
Date of Initiation	28-07-2020	21-08-2020	24-08-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last product specific inspection of firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR Compliant. Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No.IT-API/161/H/2021) dated 15-07-2021 issued by Alfa Italian Medicines Agency, the certificate specifies that the firm is operating at satisfactory level of GMP compliance. Valid for three years from date of inspection.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form-6 no. 0359/20-DRAP(K) issued on 27-01-2020 specifying 0.250Kg of minodronic Acid Hemihydrate. Cleared by DRAP (I&E) Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Provide results of analysis of relevant batch(es) of Drug Substance (0000300533) performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
2.	Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies from product manufacturer.	Method used foranalysis of API along with analytical method validation studies from product manufacturer has been provided.	Complied
3.	In CDP results were monitored for two time points only i.e 0 min and 15 min and values were calculated accordingly.	As Minodronic acid is highly soluble material in aqueous solution. the dissolution above 95% was achieved in 15min, consequently, analyst didn't run the chromatograms after 15 min, because it would become useless to perform the dissolution	%age drug release within 15 min has been verified from CDP report i.e above 95%

			after achieving 95% dissolution in 15 min.		
	4.	Provide image/snapshot/picture of Innovator Pack against which pharmaceutical equivalence study was performed. It should reveal,brand name, manufacturer, batch no. and expiry date	Provided	Manufacturer, batch no. and expiry date could not be identified due to language difference (Japanese) *Later on firm had provided translated version wherein name of manufacturer and product name was identified.*	
	5.	Results of specificity (blank, standard and placebo) has not been provided under analytical method verification study of Drug Product	Chromatograms regarding specificity parameter (blank, standard and placebo) are provided	Complied	
	6.	Assay of Drug substance was performed using UV detector wherein wavelength was adjusted at 225nm while Drug product manufacturer performed assay of product using UV detector with adjusted wavelength 218nm. Justify it	Wavelength in the assay of API was 225nm in both API and product manufacturer's analytical procedure. However, during analysis of product, analyst first performed assay on PDA detector and found that better peak was observed at 218nm instead of 225nm. The slight variation in wavelength was due to interaction of different EPI .	Justified	
	7.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied	
	8.	Applied formulation is "Minodronic Acid hydrate" same salt form has been present in innovator product/reference product as well. While Drug substance procured (as per Form 6) was Minodronic Acid hemihydrate. Clarify it	In all documents (CoA, manufacturing and testing documents) Drug substance was mentioned as Minodronic acid hydrate instead of hemihydrate Hence Minodronic Acid hemihydrate mentioned on Form -6 may be considered as typographic error.	Firm has submitted commercial invoice no. 322000041 dated 21.01.2020 wherein Drug substance mentioned as Minodronic Acid hydrate Batch No: 0000300533 Quantity: 0.25Kg Cleared by AD (I&E) Karachi dated 27.01.2020	

Decision 331st meeting: Deferred for clarification as CDP results were monitored for two time points only i.e 0 min and 15 min and more than 95% drug release within 15 min as per CDP performed by the firm.

Reply:

In this context, we would like to notify you that our analyst initially conducted the CDP test at various time intervals. The findings revealed a dissolution percentage exceeding 85% (approximately 95%) after the 15-minute sampling point in all three recommended mediums. Subsequently, the analyst repeated the dissolution at 5- and 10-minute intervals to adhere to the CDP condition, which mandates testing at a minimum of three time points. Despite performing the dissolution at three time points, the results were only reported for the 15-minute interval. However, records of tests conducted at all three time points are documented in our records. We are providing comprehensive data, including raw data, for your assessment and kindly urge you to consider the information.

Remarks: Results for CDP performed at 5min, 10 min and 15 min in all three recommended mediums have been submitted however more than 90% drug release within 15 min in all three mediums as per CDP report submitted by the firm.

482.	Name, address of Applicant / Marketing Authorization Holder	Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No.E-127,E-128 & 129, North Western Zone, Port Qasim Authority Karachi
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No.E-127,E-128 & 129, North Western Zone, Port Qasim Authority Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP inspection report dated 11-08-2020 wherein firm was GMP compliant.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-09-2012 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11606 dated No 13.05.2022
	Details of fee submitted	PKR 75,000/- Dated 25-02-2022
	The proposed proprietary name / brand name	**Minodron 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Minodronic acid hydrate…… 50mg
	Pharmacotherapeutic Group of (API)	Third generation Nitrogen containing biophosphonate
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Recalbon 50mg tablet by Ono pharmaceutical Co Ltd
	For generic drugs (me-too status)	N/A

	Name and address of API manufacturer.	PROCOS S.p.A. Via Matteotti, 249 28062 Cameri (NO) - ITALY
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No: 0000244247, 0000244249, 0000244250
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Recalbon 50mg Tablet manufactured by Ono pharmaceutical Co., Ltd. Parameters such as physical appearance, Hardness, DT, assay, dissolution was compared. Firm has submitted CDP results of their product against the innovator's product Recalbon 50mg Tablet in in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range..
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	PROCOS S.p.A. Via Matteotti, 249 28062 Cameri (NO) - ITALY		
API Lot No.	0000300522 0000300533		
Description of Pack (Container closure system)	Alu-PVC blister pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TF 01	TF 02	TF 03
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	07-2020	08-2020	08-2020
Date of Initiation	28-07-2020	21-08-2020	21-08-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last product specific inspection of the firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: The HPLC software is 21CFR Compliant. Firm as demonstrated Audit trail testing reports on testing
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No.IT-API/161/H/2021) dated 15-07-2021 issued by Alfa Italian Medicines Agency, the certificate specifies that the firm is operating at satisfactory level of GMP compliance. Valid for three years from date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form-6 no. 0359/20-DRAP(K) issued on 27-01-2020 specifying 0.250Kg of minodronic Acid Hemihydrate. Cleared by DRAP (I&E) Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Assessor:		

Sr.#	Observations	Reply	Remarks
1.	Provide RRA approval status of minodronic acid 50mg tablet. Since already provided reference of innovator/reference product is not found in PMDA or any RRA	Firm has provided reference of approved product in PMDA Japan Recalbon Tablets 50mg	Verified https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/3999026
2.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
3.	Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies from product manufacturer.	Method used for analysis of API along with analytical method validation studies from product manufacturer has been provided.	Complied
4.	Provide Drug excipients compatibility study report for croscarmellose sodium,microcrystalline cellulose and mannitol being qualitatively different from innovator product (minodronic acid 1mg tablet) or provide reference regarding innovator product (minodronic acid 50mg tablet) wherein said ingredients were found.	Firm has submitted reference regarding composition of innovator/reference product wherein said ingredients croscarmellose sodium,microcrystalline cellulose and mannitol were used. https://www.kegg.jp/medicus-bin/japic_med_product?id=00059758	Verified
5.	In CDP, results were monitored for two time points only i.e 0 min and 15 min and values were calculated accordingly.	As Minodronic acid is highly soluble material in aqueous solution. the dissolution above 95% was achieved in 15min, consequently, analystdidn't run the chromatograms after 15 min, because it would become useless to perform the dissolution after achieving 95% dissolution in 15 min.	%age drug release within 15 min has been verified from CDP report i.e above 95%

6.	Provide image/snapshot/picture of Innovator Pack against which pharmaceutical equivalence study was performed. It should reveal, brand name, manufacturer, batch no. and expiry date	Provided	Manufacturer, batch no. and expiry date could not be identified due to language difference (Japanese) *Later on firm had provided translated version wherein name ofmanufacturer and product name was identified.*
7.	Assay of Drug substance was performed using UV detector wherein wavelength was adjusted at 225nm while Drug product manufacturer performed assay of product using UV detector with adjusted wavelength 218nm. Justify it	Wavelength in the assay of API was 225nm in both API and product manufacturer's analytical procedure. However, during analysis of product, analyst first performed assay on PDA detector and found that better peak was observed at 218nm instead of 225nm. The slight variation in wavelength was due to interaction of different EPI .	
8.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Provided	Complied
9.	Applied formulation is "Minodronic Acid hydrate" same salt form has been present in innovator product/reference product as well. While Drug substance procured (as per Form 6) was Minodronic Acid hemihydrate. Clarify it	In all documents (CoA, manufacturing and testingdocuments) Drug substance was mentioned as Minodronic acid hydrate instead of hemihydrate HenceMinodronic Acid hemihydrate mentioned on Form -6 may be considered as typographic error.	Firm has submitted commercial invoice no. 322000041 dated 21.01.2020 wherein Drug substance mentioned as Minodronic Acid hydrate Batch No: 0000300533 Quantity: 0.25Kg Cleared by AD (I&E) Karachi dated 27.01.2020

Decision 331st meeting: Deferred for clarification as CDP results were monitored for two time points only i.e 0 min and 15 min and more than 95% drug release within 15 min as per CDP performed by the firm.

Reply:

In this context, we would like to notify you that our analyst initially conducted the CDP test at various time intervals. The findings revealed a dissolution percentage exceeding 85% (approximately 95%) after the 15-minute sampling point in all three recommended mediums. Subsequently, the analyst repeated the dissolution at 5- and 10-minute intervals to adhere to the CDP condition, which mandates testing at a minimum of three time points. Despite performing the dissolution at three time points, the results were only reported for the 15-minute interval. However, records of tests conducted at all three time points are documented in our records. We are providing comprehensive data, including raw data, for your assessment and kindly urge you to consider the information.

Remarks: Results for CDP performed at 5min, 10 min and 15 min in all three recommended mediums have been submitted however more than 90% drug release within 15 min in all three mediums as per CDP report submitted by the firm.
Decision: Registration Board approved the applications of Minodron 50mg Tablet and Minodron 1mg Tablet • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of Evaluator PEC-XXIII

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

a. Deferred cases

483.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	U-TAC 6.4mg tablet
	Composition	Each film coated tablet contains: Glyceryl trinitrate…… 6.4mg
	Diary No. Date of R& I & fee	Dy No. 14581 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789184 dated 07-03-2019
	Pharmacological Group	Vasodilators used in cardiac diseases ATC Code C01DA02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications, as claimed by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found in film coating
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Firm has applied for film coated tablet. In reference regulatory authority (MHRA), approved product is prolonged release oral tablet. Change in dosage form from film-coated tablet to prolonged release tablet along with prescribed fee (PKR 30,000) is required. • It is not clear whether applied product is oral or sub lingual tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision of 326th meeting of RB	**Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-083/2023 dated 11-10-2023 and No. LP/DRAP-026/2023 dated 13-04-23, stating the following: • Inspection of the facility was conducted in 02-2021wherein the panel had recommended renewal of following five sections: Tablet (General)

		Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Dosage form revised from film-coated tablet to • prolonged release along with PKR30,000 fee (Deposit Slip No.7905775438). • Applied product is oral tablet. • Me-too is Cardnit Tablet 6.4mg of M/s Atco Laboratories Limited, Karachi (Reg. No. 030299)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved as per following label claim with Innovator's Specifications. **Each prolonged release oral tablet contains:** **Glyceryl trinitrate…… 6.4mg**	
484.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	OLAM tablet 20/5mg
	Composition	Each film coated tablet contains: Amlodipine…….20mg Olmesartan Medoxomil ……5mg
	Diary No. Date of R& I & fee	Dy No. 14588 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789191 dated 07-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code C09DB02
	Type of Form	Form 5
	Finished Product Specification	Not mentioned by applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Finished product specifications are required. • Evidence of approval of applied product in reference regulatory authority is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.** • **Submission of finished product specifications.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**

	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 07-07-2023, stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Finished product complies Manufacturer's Specifications. Label claim revised as follows: • Each film coated tablet contains: Amlodipine (as besylate) .....10mg Olmesartan Medoxomil .....20mg along with PKR7500 fee (Deposit Slip No. 41609851642 dated 10-10-23) • Omsana AM Tablet 10/20mg (Me-too)
	Remarks of the Evaluator[xxiii].	Change of Manufacturer's Specifications to USP Specifications AND Revision of label claim for the complete salt as follows: "Each film coated tablet contains: Amlodipine (as besylate) .....10mg Olmesartan Medoxomil .....20mg" Along with submission of Rs.22,500/- differential fee for pre-registration change for equivalency and adjustment of weight as per salt factor.
	Decision: Approved with following label claim with USP sepcifications: "Each film coated tablet contains: Amlodipine (as besylate).....10mg Olmesartan Medoxomil .....20mg" Applicant shall submit Rs.22,500/- differential fee for pre-registration change for equivalency and adjustment of weight as per salt factor, before issuance of registration letter.	
485.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	DESVEN tablet 50mg
	Composition	Each film coated tablet contains: Desvenlafaxine…..... 50mg
	Diary No. Date of R& I & fee	Dy No. 14608 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792399 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX23
	Type of Form	Form 5
	Finished Product Specification	Not provided
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Extended release tablet (DIN 02535106) is Health Canada approved.
	Me-too status	Desven XR 50mg Tablet (For extended release tablet) Pharmevo (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Finished product specifications are not provided. • Applied product is film coated tablet. Formulation approved in reference regulatory authority (Health

		Canada) and in Pakistan is extended release tablet. Change in formulation from film coated to extended release tablet along with relevant fee is required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Latest GMP inspection report conducted within last three years.** • **Provision of finished product specifications.** • **Change in formulation from film coated to extended release tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081-B/2023 dated 07-07-2023, stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Finished product complies Manufacturer's Specifications. • Formulation changed from film coated to extended release tablet as available in reference regulatory authority along with Rs.7500/- fee vide DS No. 05302223173.
	Remarks of the Evaluator[xxiii].	Differential fee (PKR 22,500/-) shall be submitted by applicant as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration correction of composition.
	Decision: Approved with following label claim with Manufcaturer's sepcifications: **"Each film coated tablet contains:** **Desvenlafaxine.....50mg."** **Applicant shall submit Rs. 22,500/- differential fee for pre-registration correction of composition, before issuance of registration letter.**	
486.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	D-FEN SR tablet 100mg
	Composition	Each delayed release tablet contains: Diclofenac Sodium ……100mg
	Diary No. Date of R& I & fee	Dy No. 14568 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789171 dated 07-03-2019.
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, non-steroids ATC Code M01AB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available as 100mg delayed release oral tablet
	Me-too status	Not available as 100mg delayed release oral tablet
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.

		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081-B/2023 dated 07-07-2023 and No. LP/DRAP-081-C/2023 dated 11-10-2023 , stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Formulation changed from delayed release to extended release tablet as available in reference regulatory authority (USFDA) and according to the submitted me-too product. • Me-too: Dicloran SR 100 Tablet by M/s Sami Pharmaceuticals (Reg. No. 009743).
	Remarks of the Evaluator[xxiii].	Full fee (PKR 30,000/-) shall be submitted by applicant as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration variation.
	Decision: Approved as extended release tablet. Applicant shall submit PKR 30,000/- as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration variation, before issuance of registration letter.	
487.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	Skinton 20% Cream
	Composition	Each gram of cream contains: Azelaic acid..... 0.2gm/gm
	Diary No. Date of R& I & fee	Dy No. 16724 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0804196 dated 07-03-2019
	Pharmacological Group	Other anti-acne preparations for topical use ATC Code D10AX03
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azelex 20% topical cream USFDA Approved
	Me-too status	Ezalic 20% cream Evolution Pharmaceuticals (Pvt.) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Change of label claim according to composition given in USFDA, as follows: "Each gram of cream contains Azelaic acid..... 0.2 gm (20% w/w)" along with requisite fee.
	Decision of 327th meeting of RB	**Deferred for following:** • **Change of label claim according to composition given in USFDA, as follows:** • **"Each gram of cream contains Azelaic acid.....0.2 gm (20% w/w)" along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081-B/2023 dated 07-07-2023, stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Change of label claim according to composition given in USFDA, as follows: • "Each gram of cream contains Azelaic acid..... 0.2 gm (20% w/w)" along with PKR 7500/- fee (deposit Slip No. 886924243338).
	Remarks of the Evaluator[xxiii].	
	Decision: Approved with following label claim: "Each gram of cream contains Azelaic acid.....0.2 gm (20% w/w)".	
488.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	LIGAIN 5% OINTMENT
	Composition	Each gram of cream contains: Lidocaine(Lignocaine).....0.05gm/gm
	Diary No. Date of R& I & fee	Dy No. 14572 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789175 dated 07-03-2019
	Pharmacological Group	Local anaesthetic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Xyloaid 5% Ointment Reg. No. 23075
	GMP status	Last GMP inspection conducted on 10-07-2019

	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Change label claim to read as follows: "Each gram of ointment contains: Lidocaine(Lignocaine)……0.05gm", along with submission of requisite fee. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required.
	Decision of 327th meeting of RB	**Decision: Deferred for following:** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting,** • **Change label claim to read as follows:** **"Each gram of ointment contains: Lidocaine(Lignocaine)……0.05gm", along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081-B/2023 dated 07-07-2023 and No. LP/DRAP-081-C/2023 dated 11-10-2023, stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Label claim changed as follows according to product approved in USFDA: "Each gram of ointment contains: Lidocaine(Lignocaine)..... 0.05gm", along with PKR 7500/- fee (deposit Slip No. 11458829).
	Remarks of the Evaluator[xxiii].	
	Decision: Approved with following label claim: **"Each gram of ointment contains:** **Lidocaine(Lignocaine) .....0.05gm".**	
489.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	FLAVO tablet 500mg
	Composition	Each film coated tablet contains: Micronized purified flavonoid fraction
	Diary No. Date of R& I & fee	Dy No. 14593 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789197 dated 07-03-2019
	Pharmacological Group	Vasoprotective
	Type of Form	Form 5
	Finished Product Specification	USP Specifications, as stated by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed as complete composition is not provided

	Me-too status	Not found as complete composition is not provided
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Master formulation describing quantities of actives and excipients along with the justification/role each ingredient. • Label claim does not include quantity of API. Label claim needs to be revised according to the master formulation. • Finished product is not available in USP. Change of specifications from USP to Manufacturer's specifications along with relevant fee is required. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision of 327th meeting of RB	**Decision: Deferred for following:** • **Latest GMP inspection report conducted within last three years.** • **Submission of master formulation describing quantities of actives and excipients along with the justification/role each ingredient.** • **Revision of label claim as per master formulation to include quantity of API.** • **Justification of submitted finished product specifications, since firm has claimed USP specifications whereas USP monograph is not available for applied formulation. In case of change from USP to Manufacturer's specifications, firm shall submit prescribed fee as per notification No.F.7-11/2012- B&A/DRAPdated 13-07-2021.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081-B/2023 dated 07-07-2023 and No. LP/DRAP-081-C/2023 dated 11-10-2023, stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Reference regulatory authority is CIMA, Spain. • Label claim changed as follows according to product

		approved in CIMA: "Each film coated tablet contains: Purified flavonic fraction in micronized form 500mg containing Diosmin 90% ....450mg Flavonoids expressed in Hesperidin 10% ... 50mg" • Change of specifications from USP to Manufacturer's Specifications along with PKR 7500/- fee (deposit Slip No.04201494768) • Me-too Tablet Daflon by M/s Servier (Reg. No. 014694)
	Remarks of the Evaluator[xxiii].	Differential fee (PKR 22,500/-) shall be submitted by applicant as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration correction of composition.
	Decision: Approved with USP Specifications and following label claim: **"Each film coated tablet contains:** **Purified flavonic fraction in micronized form 500mg containing** **Diosmin 90%.....450mg** **Flavonoids expressed in Hesperidin 10% ...50mg."** **Applicant shall submit differential fee (PKR 22,500/-) as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration correction of composition, before issuance of registration letter.**	
490.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	LORA-P CR 5mg/120mg tablet
	Composition	Each film coated controlled release tablet contains: Loratidine USP…..... 5mg Pseudoephedrine Sulphate USP 120mg
	Diary No. Date of R& I & fee	Dy No. 14573 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789176 dated 07-03-2019
	Pharmacological Group	Nasal decongestants for systemic use ATC Code R01BA52
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Claritin-D 12 hour extended release tablet Bayer Healthcare LLC USFDA Approved
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Previous remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Change of master formulation to include Loratidine is required along with requisite fee. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision of 327th meeting of RB	**Decision: Deferred for following:** • **Latest GMP inspection report conducted within last three years.** • **Change of master formulation to include Loratidine along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**

		• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081-B/2023 dated 07-07-2023 and No. LP/DRAP-081-C/2023 dated 11-10-2023, stating the following: • Inspection of the facility was conducted in 02-2021 wherein the panel had recommended renewal of following five sections: Tablet (General) Capsule (General) Cream/Ointment/Gel (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) • Master formulation changed to include API Loratidine along with PKR 7500/- fee (deposit Slip No.91087133825) • Me-too Tablet Softin-P by M/s Werrick (Reg. No. 060094)
	Remarks of the Evaluator[xxiii].	Differential fee (PKR 22,500/-) shall be submitted by applicant as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration correction of composition.
	Decision: Approved with Manufacturer's Specifications. **Applicant shall submit differential fee (PKR 22,500/-) as prescribed vide SRO 496(I)/2023 dated 17.04.2023 for pre-registration correction of composition , before issuance of registration letter.**	

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

a. New DML

491.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16837 dated 06-07-2023
	Details of fee submitted	PKR 30,000/- Dated 27-06-2023
	The proposed proprietary name / brand name	**ESSOGM 20mg Capsule**
	Strength / concentration of drug of Active	Each Capsule Contains:

	Pharmaceutical ingredient (API) per unit	Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole…20mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in hard gel capsules
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1x10's, 2x7's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 20mg capsule (USFDA Approved)
	For generic drugs (me-too status)	Nexum 20mg capsule of M/s Getz Pharma Pakistan (Pvt) Ltd, Karachi (Reg.No. 033890)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000806) (Semi-basic)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications,

		analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, working standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Nexum 20mg capsule manufactured by M/s Getz Pharma Pakistan (Pvt) Ltd, Karachi. Firm has submitted CDP results of their product against the comparator product Nexum 20mg capsule in 3 dissolution media. The value for similarity factor is in the acceptable range
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000806) (Semi-basic)		
API Lot No.	EMZ046515		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CPT01	CPT02	CPT03
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	05-09-2022	05-09-2022	05-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Drug Regulatory Authority of Pakistan renewed w.e.f 02-12-2019 and copy of GMP Certificate (No. F. 3-26/2019-Addl. Dir. (QA & LT-I)-56 dated 22-08-2022 issued on the basis of inspection conducted on 14-06-2022. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 14-06-2022 specifying purchase of Esomeprazole Magnesium EC Pellets 8.5%.

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

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.5**	GMP certificate/ GMP report issued by DRAP within the last three years of drug product manufacturer shall be submitted.	AGM Pharmaceuticals is a newly established unit and we are currently in the registration phase. We have successfully obtained approval for five products in the 330th RB meeting held on July 24th-26th, 2023**. *Our commercial production has not commenced as of now.*** Once production begins, we plan to pursue GMP certification.
2.	**2.3.R.1.1**	Pellets used in stability batches of Essogm 20mg have an assay value of 102.24% as given in CoA and BMRs. The dispensed weight/fill weight per capsule is given as 237.05mg in BMRs. Justify with complete calculations.	Justified with complete calculations.

Decision: Approved.

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

492.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 16836 dated 06-07-2023
	Details of fee submitted	PKR 30,000/- Dated 22-06-2023
	The proposed proprietary name / brand name	**ESSOGM 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole…40mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in hard gel capsules
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1x10's, 2x7's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 40mg capsule (USFDA Approved)
	For generic drugs (me-too status)	Nexum 40mg capsule of M/s Getz Pharma Pakistan (Pvt) Ltd, Karachi (Reg. No. 033891)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000806) (Semi-basic)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, working standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Nexum 40mg capsule manufactured by M/s Getz Pharma Pakistan (Pvt) Ltd, Karachi. Firm has submitted CDP results of their product against the comparator product Nexum 40mg capsule in 3 dissolution media. The value for similarity factor is in the acceptable range
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000806) (Semi-basic)		
API Lot No.	EMZ046487		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CPT04	CPT05	CPT06
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	05-09-2022	05-09-2022	05-09-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Drug Regulatory Authority of Pakistan renewed w.e.f 02-12-2019 and copy of GMP Certificate (No. F. 3-26/2019-Addl. Dir. (QA & LT-I)-56 dated 22-08-2022 issued on the basis of inspection conducted on 14-06-2022. The

		certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 14-06-2022 specifying purchase of Esomeprazole Magnesium EC Pellets 22.5%.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.5**	GMP certificate/ GMP report issued by DRAP within the last three years of drug product manufacturer shall be submitted.	AGM Pharmaceuticals is a newly established unit and we are currently in the registration phase. We have successfully obtained approval for five products in the 330th RB meeting held on July 24th-26th, 2023. ***Our commercial production has not commenced as of now.*** Once production begins, we plan to pursue GMP certification.

Decision: Approved.

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

493.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22610 dated 14-09-2023
	Details of fee submitted	PKR 30,000/- Dated 18-11-2022
	The proposed proprietary name / brand name	**LAPAZOLE 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Lansoprazole as Enteric Coated Pellets….30mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Pharmaceutical form of applied drug	White to off white enteric coated pellets filled in hard gel capsules
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1x10's, 2x7's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lansoprazole 30mg Gastro Resistant capsules (MHRA Approved)
	For generic drugs (me-too status)	Selanz 30mg capsule of M/s Searle Pakistan Ltd., C-14 Mangopir Road SITE Karachi. (Reg.No. 110185)
	Name and address of API manufacturer.	M/s Pharma Zone Chemicals (Pvt) Ltd, Plot No. 37, Sunder Industrial Estate, Lahore. (DML No. 000861) (Semi-basic)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, working standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Selanz 30mg capsule manufactured by M/s Searle Pakistan Ltd., Karachi. Firm has submitted CDP results of their product against the comparator product Selanz 30mg capsule in 3 dissolution media. The value for similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharma Zone Chemicals (Pvt) Ltd, Plot No. 37, Sunder Industrial Estate, Lahore. (DML No. 000861) (Semi-basic)		
API Lot No.	LEC-8.5-045		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRC-022	TRC-023	TRC-024
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	20-11-2021	20-11-2021	20-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate Ref. No. 43/2022-DRAP (AD-00196339815-153) dated 07-04-2022 issued on the basis of evaluation conducted on 30-03-2022.The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 15-11-2021 specifying purchase of Lansoprazole Pellets 8.5%.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

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

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.S.5 & 3.2.P.6**	Justify the use of working standard from M/s Vision Pharmaceuticals (Pvt) Ltd which is neither the drug substance manufacturer nor manufacturer of pharmacopoeial reference standards.	Since the reference standard of M/s Pharmazone was expired and alternate was not available at that time from M/s Pharmazone so we arranged from M/s Vision Pharmaceuticals of same Pharmacopoeial grade. *Applicant has committed to using reference standard from relevant API manufacturer for quality testing of commercial batches.*
2.	**3.2.P.2.2.1**	Complete pharmaceutical equivalence report shall be submitted stating all parameters present in the finished product specifications (USP) as the report does not include the results of content uniformity test.	We have considered content uniformity as in-process test we have not performed in Finished Product testing stage. But We have now revised our finished Product specifications (attached) Our Product is expired now details as below: Mfg Date: 11-2021 Exp Date: 10-2023 We hereby commit that we will perform the content uniformity test in 1st commercial batch and will submit the complete data.
3.	**2.3.R.1.1**	Provide copies of BMRs of all three stability batches of drug product as the attached documents are blank BMRs.	BMRs are submitted

Decision: Approved.

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

494.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25421 dated 20-10-2023
	Details of fee submitted	PKR 30,000/- Dated Nil
	The proposed proprietary name / brand name	**AG-PIME 500mg IM/IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Sterile powder of Cefepime HCl with L-Arginine Equivalent to Cefepime…500gm
	Pharmacotherapeutic Group of (API)	Fourth generation cephalosporin
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime for injection 500mg, 1g, 2g (USFDA Approved)
	For generic drugs (me-too status)	Avepime Injection 500mg of M/s Aventek Pharmaceuticals, Lahore (Reg. No. 059586)
	Name and address of API manufacturer.	Sterile India Pvt Ltd, Plot No. 100 & 118G, Phase IV, Sector-56, HSIIDC, Kundi Haryana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical

		procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Daypime 500mg IV/IM Injection manufactured by High-Q Pharmaceuticals, Karachi. Since the applied product is a parenteral hence CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Sterile India Pvt Ltd, Plot No. 100 & 118G, Phase IV, Sector-56, HSIIDC, Kundi Haryana India.		
API Lot No.	SI/CFP/00540722		
Description of Pack (Container closure system)	Clear glass vial with rubber stopper having flip off seal		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRV-022	TRV-023	TRV-024
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	17-10-2022	17-10-2022	17-10-2022
Date of Initiation	02-11-2022	02-11-2022	02-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule

		AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 12/80-IDrug-I-2022/5539 dated 01-08-2022 issued by Food and Drugs Control Administration Haryana, India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Himedic Pharmaceuticals Pvt Ltd, Lahore dated 28-09-2022 specifying 10Kg loan of Cefepime Hydrochloride. Firm has also submitted clearance certificate dated 29-08-2022 specifying import of 20kg Cefepime HCl L-Arginine. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**2.3.R.1.1**	Provide copies of BMRs of all three stability batches of drug product as the attached documents are blank BMRs.	Submitted
2.	**2.3.S.6 & 2.3.P.5.4**	Manufacturing date of stability batches of Ag-pime 500mg is 17-10-22 whereas the manufacturing date of stability batches of Ag-pime 1g is 19-10-22. Same batch ofdrug substance supplied in 10kg packing isused for both strengths. Justify how thesterility of the drug substance wasmaintained in an open container for two days.	We have received Cefepime in two containers of 2 x 5kg from Himedic as loan. We have used 1 x 5kg container for the trial batches of 500mg injection (IM/IV) and 1 x 5kg container use in 1g injection (IM/IV)
3.	**3.2.P.1**	Details of diluent including brand name, manufacturer's name, specifications, pack size, container closure system and registration number shall be submitted.	Details of diluent are as follows: For 500mg Injection:- Brand Name: Mini WFI 5ml Manufacturer Name: Frontier Dextrose Ltd, Haripur Specification: BP Pack Size: 1 x 5ml Container Closure: 5ml plastic Ampule Reg. Number: 076881

Decision: Approved.

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
495.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25422 dated 19-10-2023
	Details of fee submitted	PKR 30,000/- Dated Nil
	The proposed proprietary name / brand name	**AG-PIME 1g IM/IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Sterile powder of Cefepime HCl with L-Arginine Equivalent to Cefepime…1gm
	Pharmacotherapeutic Group of (API)	Fourth generation cephalosporin
	Pharmaceutical form of applied drug	Dry powder for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime for injection 500mg, 1g, 2g (USFDA Approved)
	For generic drugs (me-too status)	Avepime Injection 1g of M/s Aventek Pharmaceuticals, Lahore (Reg. No. 059585)
	Name and address of API manufacturer.	Sterile India Pvt Ltd, Plot No. 100 & 118G, Phase IV, Sector-56, HSIIDC, Kundi Haryana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Cefstar 1g IV/IM Injection manufactured by Barret Hodgson Pvt Ltd. Since the applied product is a parenteral hence CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Sterile India Pvt Ltd, Plot No. 100 & 118G, Phase IV, Sector-56, HSIIDC, Kundi Haryana India.		
API Lot No.	SI/CFP/00540722		
Description of Pack (Container closure system)	Clear glass vial with rubber stopper having flip off seal		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRV-025	TRV-026	TRV-027

Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	19-10-2022	19-10-2022	19-10-2022
Date of Initiation	04-11-2022	04-11-2022	04-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 12/80-IDrug-I-2022/5539 dated 01-08-2022 issued by Food and Drugs Control Administration Haryana, India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Himedic Pharmaceuticals Pvt Ltd, Lahore dated 28-09-2022 specifying 10Kg loan of Cefepime Hydrochloride. Firm has also submitted clearance certificate dated 29-08-2022 specifying import of 20kg Cefepime HCl L-Arginine. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**2.3.R.1.1**	Provide copies of BMRs of all three stability batches of drug product as the attached documents are blank BMRs.	Submitted
2.	**2.3.S.6 & 2.3.P.5.4**	Manufacturing date of stability batches of Ag-pime 500mg is 17-10-22 whereas the manufacturing date of stability batches of Ag-pime 1g is 19-10-22. Same batch of drug substance supplied in 10kg packing is used for both strengths. Justify how the sterility of the drug substance was maintained in anopen container for two days.	We have received Cefepime in two containers of 2 x 5kg from Himedic as loan. We have used 1 x 5kg container for the trial batches of 500mg injection (IM/IV) and 1 x 5kg container use in 1g injection (IM/IV)
3.	**3.2.P.1**	Details of diluent including brand name, manufacturer's name, specifications, pack size, container closure system and registration number shall be submitted.	Details of diluent is as under for 1g Injection Brand Name: Zee-Inject 10ml

			Manufacturer Name: Shazeb Pharma, Haripur Specification: BP Pack Size: 1 x 10ml Container Closure: 10ml plastic Amp. Reg. Number: 073339	

Decision: Approved.

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

496.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22609 dated 14-09-2023
	Details of fee submitted	PKR 30,000/- Dated 24-03-2023
	The proposed proprietary name / brand name	**F-ZOLE 150mg Capsule** **FLUZONE 150mg Capsule** **FLU-GM 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluconazole… 150mg
	Pharmacotherapeutic Group of (API)	Antimycotics For Systemic Use
	Pharmaceutical form of applied drug	Hard gelatin capsule filled with white to off white powder
	Reference to Finished product specifications	BP
	Proposed Pack size	1's, 4's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azocan 150mg capsule (MHRA Approved)
	For generic drugs (me-too status)	Fantizol Capsule of M/s Apex Pharmaceuticals (Pvt) Ltd, Karachi (Reg.No. 073551)
	Name and address of API manufacturer.	Horster Biotek Pvt, Ltd. Khasra No. 259, Plot No. 1&2, Gram Sukhlia, Sanwer Road, Industrial Area, Indore M.P, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Diflucan Capsule 150mg manufactured by M/s Pfizer Pakistan Ltd. Firm has submitted CDP results of their product against the innovator's product Diflucan Capsule 150mg in three dissolution media. The similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Horster Biotek Pvt, Ltd. Khasra No. 259, Plot No. 1&2, Gram Sukhlia, Sanwer Road, Industrial Area, Indore M.P, India.
API Lot No.	HBPL/FCZ/20-21/010
Description of Pack	Alu-PVC Blister

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRC-016	TRC-017	TRC-018
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	03-12-2021	03-12-2021	03-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. INDBGMP202211255) dated 30-11-2022 issued by Food and Drugs Control Administration Madhya Pradesh, India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Fahmir Pharma Pvt Ltd, Lahore dated 29-11-2021 specifying 1Kg loan of Fluconazole. Firm has also submitted clearance certificate dated 19-11-2020 specifying import of 25kg Fluconazole. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**3.2.S.5 & 3.2.P.6**	The submitted CoA of reference standard in 3.2.S.5 is not legible. CoA of reference standard including source and lot number shall be submitted.	CoA of Fluconazole USP raw material is submitted *whereas COA of reference standard is required.*
2.	**2.3.R.1.1**	Provide copies of filled BMRs of all three stability batches of drug product.	Submitted.

Decision: Deferred for submission of CoA of reference/working standard used for analysis of stability batches along with details of source/grade and lot number of primary reference standard against which it was standardized.		
497.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25449 dated 20-10-2023
	Details of fee submitted	PKR 30,000/- Dated Nil
	The proposed proprietary name / brand name	AG-COBAL 500mcg Tablet MECOBALAGM 500mcg Tablet MECOGM 500mcg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sugar coated tablet contains: Mecobalamin…500mcg
	Pharmacotherapeutic Group of (API)	Vitamin B12 (cyanocobalamin and analogues)
	Pharmaceutical form of applied drug	Sugar coated tablet
	Reference to Finished product specifications	JP
	Proposed Pack size	1 x 10’s, 2 x 10’s, 3x 10’s, 10 x10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA Approved
	For generic drugs (me-too status)	Methycobal Tablet of M/s Hilton Pharma (Pvt) Ltd, Karachi (Reg.No. 010314)
	Name and address of API manufacturer.	Hebei Yuxing Bio Engineering Co., Ltd. Xicheng District, Nigjin County, Xing Tai City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, eorking standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturingprocess and process control, process validationprotocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Methycobal Tablet 500mcg of M/s Hilton Pharma (Pvt) Ltd, Karachi. Firm has submitted CDP results of their product against the innovator's product Methycobal Tablet 500mcg in three dissolution media. The similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Yuxing Bio Engineering Co., Ltd. Xicheng District, Nigjin County, Xing Tai City, Hebei Province, China.		
API Lot No.	M201104		
Description of Pack (Container closure system)	Red Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-032	TRT-033	TRT-034
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	23-11-2021	23-11-2021	23-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HF20190142) dated 30-11-2019 issued by Hebei Drug Administration, People's Republic of China. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s N.S Pharma Pvt Ltd, Lahore dated 12-11-2021 specifying 20gram loan of Mecobalamin. Firm has also submitted clearance certificate dated 04-02-2021 specifying import of 1kg Mecobalamin. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**2.3.S.5 & 3.2.S.5**	Justify the use of working standard from M/s Mahima Life Sciences which is neither the drug substance manufacturer nor manufacturer of pharmacopoeial reference standards.	We have used the working standard of Mahima Life Sciences for stability data analysis and we have provided its Certificate of analysis. At initial, the received working standard with material was expired so we arranged another one from Mahima Life Sciences for analytical purpose as of same pharmacopeia grade.
2.	**2.3.S.5 & 3.2.S.5**	CoA of reference standard should include source and lot number.	CoA of used working standard is submitted with source and lot no. information. *However, the CoA submitted is of secondary reference standard and does not include details of traceability to primary reference standard.*
3.	**3.2.S.4**	Drug product manufacturer shall submit complete batch analysis results (as per pharmacopeia) of the relevant batch of drug substance along with supporting data since in	Revised Certificate of analysis of used material with all test results as per pharmacopeia is provided.

		the submitted CoA, test results of related substances are not stated.	
4.	**3.2.P.2.2.1**	Results of content uniformity testing of applied and comparator product shall be submitted in pharmaceutical equivalence report along with supporting data/evidence since the content uniformity is part of JP monograph of finished product.	We have revised the finished product specification as per JP Monograph. Our Product is expired now, details as below: Mfg Date:11-2021 Exp Date: 10-2023 We commit that we will perform the content uniformity test in 1st commercial batch and will submit the complete data with evidence.
5.	**3.2.P.5.1 & 3.2.P.5.2**	Revise the finished product specifications and analytical procedures as per JP monograph.	We have revised the finished product specification as per JP Monograph.
6.	**3.2.P.5.4**	Results of content uniformity testing of stability batches shall be submitted along with supporting data/evidence since the content uniformity is part of JP monograph of finished product.	We have performed the uniformity of content by way of weight variation test but now we have revised the finished of product specification as per JP Monograph. Our Product is expired now details as below: Mfg Date:11-2021 Exp Date: 10-2023 We commit that we will perform the content uniformity test in 1st commercial batch and will submit the complete data with evidence.
7.	**2.3.R.1.1**	Provide copies of filled BMRs of all three stability batches of drug product.	BMRs are submitted

Decision: Approved. Firm shall submit fee of Rs. 7,500/- prescribed vide SRO 496(I)/2023 dated 17-04-2023 for change of drug product specifications before issuance of registration letter.

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

498.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 17465 dated 12-07-2023
	Details of fee submitted	PKR 30,000/- Dated 22-06-2023
	The proposed proprietary name / brand name	**FEMIC 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Famotidine…40mg
	Pharmacotherapeutic Group of (API)	H-2 Receptor Antagonist
	Pharmaceutical form of applied drug	White, oblong, biconvex, film coated tablet scored on one side
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's, 2 x 10's, 3 x 10's, 10 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pepcid Tablet (USFDA Approved)
	For generic drugs (me-too status)	Famoxo 40mg Tablet of M/s Horizon Healthcare, Lahore (Reg.No. 100844)
	Name and address of API manufacturer.	Vaasavaa Pharmaceuticals, Plot No. C-216 MIDC Chincholi, Solapur, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures,

		verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure systemand stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Pepcidine Tablet 40mg manufactured by Aspin Pharma. Firm has submitted CDP results of their product against the comparator product Pepcidine Tablet 40mg in 3 dissolution media.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vaasavaa Pharmaceuticals, Plot No. C-216 MIDC Chincholi, Solapur, India.		
API Lot No.	FAM0321060		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-010	TRT-011	TRT-012
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	07-12-2021	07-12-2021	07-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Batala Pharmaceuticals, Gujranwala dated 23-11-2021 specifying 250gram loan of Famotidine. Firm has also submitted clearance certificate dated 27-05-2021 specifying import of Famotidine. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response of the applicant
1.	**2.3.R.1.2**	The attached blank master production document/BMR is of Pantoprazole instead of Famotidine.	Submitted.
2.	**3.2.S.4 & 3.2.P.4**	ICH guidelines recommend that Analytical method verification studies assess accuracy by covering the specified concentration range with a minimum of three concentrations with at least nine determinations. However, you have assessed two replicates of five different concentrations. Justify.	Revised Analytical method verification reort submitted.
3.	**3.2.S.4**	Analytical method verification report is not signed. Submit signed report.	Signed report submitted.
4.	**3.2.P.3.2**	Product approved in USFDA contains the following inactive ingredients: hydroxypropyl cellulose, hydroxypropyl methylcellulose, iron oxides, magnesium stearate, microcrystalline cellulose, corn starch, talc, and titanium dioxide whereas the applied product contains the following excipients: Starch, lactose, primojel, magnesium stearate and croscarmellose sodium. Clarify and also submit drug-excipient and excipient-excipient compatibility studies.	Aplicant has submitted drug-excipient and excipient-excipient compatibility studies.
5.	**3.2.P.8**	Submit legible copy of commercial invoice for the import of API since the quantity imported cannot be read from the attached copy.	Submitted.
6.	**3.2.P.8**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Submitted.

Decision: Approved.

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

499.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17464 dated 12-07-2023
	Details of fee submitted	PKR 30,000/- Dated 16-08-2023
	The proposed proprietary name / brand name	**ARTHOGM 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric Coated Tablet Contains: Diclofenac Sodium…50mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Pharmaceutical form of applied drug	Enteric coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's, 2 x 10's, 3 x 10's, 10 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Voltaren Delayed Release Oral Tablet (USFDA Approved)
	For generic drugs (me-too status)	Dicmaf 50mg enteric coated tablet of M/s Mafins Pharma (Reg. No. 79884)
	Name and address of API manufacturer.	Aarti Drugs Ltd, Plot No. G-60, MIDC, Tarapur, Taluka Palghar, District Thane-401 506, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ±

		5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure systemand stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Voltral 50mg Tablet manufactured by Novartis Pharma Pakistan Ltd. Firm has submitted CDP results of their product against the comparator product Voltral 50mg Tablet in 3 dissolution media.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Aarti Drugs Ltd, Plot No. G-60, MIDC, Tarapur, Taluka Palghar, District Thane-401 506, Maharashtra, India.		
API Lot No.	DFS/11040151		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-007	TRT-008	TRT-009
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	29-11-2021	29-11-2021	29-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 6102298) dated 07-09-2022 issued by Food and Drugs Administration Maharashtra State India. The certificate specifies that the firm was operating at

		satisfactory level of GMP compliance. The certificate is valid till 06-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Batala Pharmaceuticals, Gujranwala dated 23-11-2021 specifying 250gram loan of Diclofenac Sodium. Firm has also submitted clearance certificate dated 15-06-2021 specifying import of 1000kg Diclofenac Sodium. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response of applicant
1.	**2.3.R.1.1**	Provide copies of BMRs of all three stability batches of drug product as the attached documents are blank BMRs of Pantoprazole.	Submitted.
2.	**3.2.S.4 & 3.2.P.4**	ICH guidelines recommend that Analytical method verification studies assess accuracy by covering the specified concentration range with a minimum of three concentrations with at least nine determinations. However, you have assessed two replicates of five different concentrations. Justify.	Revised analytical method verification report is submitted.
3.	**3.2.P.3.2**	The applied product contains starch as a binder whereas starch is not included in the formulation of product approved in reference regulatory authority. Justify and also submit drug-excipient and excipient-excipient compatibility studies.	Applicant has submitted drug-excipient and excipient-excipient compatibility studies.

Decision: Approved.

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

500.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 20804 dated 23-08-2023
	Details of fee submitted	PKR 30,000/- Dated 16-08-2023
	The proposed proprietary name / brand name	**MEFLAM 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Diclofenac Potassium…50mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's, 2 x 10's, 3 x 10's, 10 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Dicloflex-P 50mg film coated tablet of M/s MKB Pharmaceuticals (Pvt) Ltd (Reg. No. 102825)
	Name and address of API manufacturer.	Aarti Drugs Ltd, Plot No. G-60, MIDC, Tarapur, Taluka Palghar, District Thane-401 506, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60

		months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure systemand stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Artimov-K 50mg Tablet of Barret & Hodgson (Pvt) Ltd., F/423 SITE Karachi., Karachi. Firm has submitted CDP results of their product against the comparator product Artimov-K 50mg Tablet in 3 dissolution media.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Aarti Drugs Ltd, Plot No. G-60, MIDC, Tarapur, Taluka Palghar, District Thane-401 506, Maharashtra, India.		
API Lot No.	DFK/10090112		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-001	TRT-002	TRT-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	26-11-2021	26-11-2021	26-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 6102298) dated 07-09-2022 issued by Food and Drugs Administration Maharashtra State India. The certificate specifies that the firm was operating at

		satisfactory level of GMP compliance. The certificate is valid till 06-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Batala Pharmaceuticals, Gujranwala dated 23-11-2021 specifying 250gram loan of Diclofenac Potassium. Firm has also submitted clearance certificate dated 12-10-2020 specifying import of 5000kg Diclofenac Potassium. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response of applicant
1.	**2.3.R.1.1**	Provide copies of BMRs of all three stability batches of drug product as the attached documents are blank BMR templates.	Submitted.

Decision: Approved.

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

501.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.**
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 10-11-2021 on the basis of inspection conducted on 25-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) section, Capsule (general) section and Dry Powder Injection (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 20803 dated 23-08-2023
	Details of fee submitted	PKR 30,000/- Dated 16-08-2023

	The proposed proprietary name / brand name	**PIROGM 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Piroxicam as Beta Cyclodextrin…20mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory And Antirheumatic, Non-Steroids
	Pharmaceutical form of applied drug	Uncoated tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1 x 10's, 2 x 10's, 3 x 10's, 10 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Brexin Tablet (ANSM Approved)
	For generic drugs (me-too status)	Brexin 20mg tablet of M/s Chiesi Pharmaceuticals (Pvt) Ltd (Reg. No. 10637)
	Name and address of API manufacturer.	Kaifeng Pharmceutical Group Co., Ltd, No. 1 Yunan Street, Kaifeng, Henan, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing

		process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, working standard or materials, container closure systemand stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Brexin 20mg Tablet of M/s Chiesi Pharmaceuticals Pvt Ltd, Lahore. Firm has submitted CDP results of their product against the comparator product Brexin 20mg Tablet of M/s ChiesiPharmaceuticals Pvt Ltd, Lahore in 3 dissolution media.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance and analytical method validation study reports of drug product.

STABILITY STUDY DATA

Manufacturer of API	Kaifeng Pharmceutical Group Co., Ltd, No. 1 Yunan Street, Kaifeng, Henan, China.		
API Lot No.	K20-011		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT-028	TRT-029	TRT-030
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	10-12-2021	10-12-2021	10-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Following five products were approved in 330th meeting of RB: Cetec 10 mg Tablet AG-Zole 40mg Capsule AG-Zole 20mg Capsule Pirogm 20mg Capsule Ag-CIP 250mg Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HA20190069) dated 29-09-2019 issued by Henan Province Drug Administration, China Food and Drug Administration. The certificate specifies that the firm was operating at satisfactory level of GMP compliance. The certificate is valid till 28-09-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted loan letter from M/s Fahmir Pharma Pvt Ltd, Sheikhupura dated 07-12-2021 specifying loan of Piroxicam Beta Cyclodextrin.

		Firm has also submitted clearance certificate dated 09-10-2020 specifying import of 100kg Piroxicam Beta Cyclodextrin. The clearance certificate is issued by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response of the applicant
1.	**2.3.R.1.1**	Provide copies of BMRs of all three stability batches of drug product.	Submitted.

Decision: Approved.

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

Case no. 03 Registration applications of newly granted DML (Veterinary)

a. Deferred Cases

502.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals (Pvt) Ltd, 0.5 Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan (DML No.000970) Oral Liquid/Drench (General) Veterinary Section
	Brand Name +Dosage Form + Strength	Bronchi Poul-10% Oral Liquid
	Composition	Each ml Contains: Bromhexine HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 14690 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.6326629018
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 450 ml,500 ml,1000 ml,5000ml; Decontrolled
	Me-too status	Not confirmed
	GMP status	Not applicable; New License
	Previous remarks of the Evaluator[xxiii].	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision of 330th meeting of RB	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. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.
	Reply of Applicant	Me-too status is as follows:

		Ebrom-Lytic 10% Oral Liquid of M/s Vetec Laboratories, Rawalpindi. (Reg. No. 099317)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
503.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals (Pvt) Ltd, 0.5 Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan (DML No.000970) Oral Liquid/Drench (General) Veterinary Section
	Brand Name +Dosage Form + Strength	Tilasim-30 Oral Liquid
	Composition	Each ml Contains: Tilmicosin Phosphate Eq. to Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 14685 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No. 245588206960
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 450 ml,1000 ml, 5000ml; Decontrolled
	Me-too status	Submitted for 250mg/ml strength
	GMP status	Not applicable, New License
	Previous remarks of the Evaluator[xxiii].	Name of applied product on cover letter and fee challan is Tilasim-30 Oral liquid. However, composition given on Form 5 is stated above (250mg/ml). This strength has already been applied vide Dy.No 14686 dated 12-06-2023; firm may be advised to submit revised/correct composition of the applied product (300mg/ml) on complete Form 5 along with full fee of registration (Rs.30,000)
	Decision of 330th meeting of RB	Deferred for clarification regarding applied strength since name of applied product on cover letter and fee challan is Tilasim-30 Oral liquid whereas composition given on Form 5 is of Tilasim-25 Oral liquid (250mg/ml) which has already been applied vide Dy. No 14686 dated 12-06-2023. The Board further decided that the applicant shall submit the response within 1 month of publication of the minutes.
	Reply of Applicant	The label claim of Tilasim-25 Oral liquid applied vide Dy. No 14686 dated 12-06-2023 is as follows: Each ml Contains: Tilmicosin Phosphate …250mg/ml Whereas the label claim of instant product is as follows: Each ml Contains: Tilmicosin Phosphate *Eq. to Tilmicosin*…250mg So both formulations are different. Me-too of the instant product is Tilbar Oral Liquid of M/s Baariq Pharmaceuticals, Lahore (reg. No. 089818).
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	

Case no. 05 Miscellaneous

Following one application was approved in 331st meeting of the Registration Board held on 31st October -02nd November, 2023. The strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit was inadvertently mentioned as follows during drafting of minutes:

"Each capsule contains:
Dexlansoprazole dual delayed release pellets 22.5% equivalent to Dexlansoprazole…….30mg"

Whereas the strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit in the submitted application dossier was as follows:

"Each capsule contains:
Dexlansoprazole dual delayed release pellets 22.5% equivalent to Dexlansoprazole…….60mg".

Submitted for consideration by the Board.

504.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt) Ltd, 16km Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt) Ltd, 16km Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Valid GMP certificate is not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted cGMP compliance inspection report dated 04-02-2020 wherein it was stated that Capsule (non-antibiotic) section was available.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 20637 dated 21-07-2022
	Details of fee submitted	PKR 30,000/- Deposit Slip No. 824074451387
	The proposed proprietary name / brand name	**Dexlanz 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole dual delayed release pellets 22.5% equivalent to Dexlansoprazole…….30mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Pharmaceutical form of applied drug	Hard gelatin capsules filled with enteric coated pellets
	Reference to Finished product specifications	In-house Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant Capsule (USFDA Approved)
	For generic drugs (me-too status)	Delanzo DDR Capsule of M/s Sami Pharmaceuticals Pvt Ltd (Reg.No. 89146)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road. (DML No. 000806) (Semi-basic)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, specifications,

		analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, working standard, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator/comparator product Delanzo 60mg Capsule manufactured by M/s Sami Pharmaceuticals Pvt Ltd. Firm has submitted CDP results of their product against the comparator product Delanzo 60mg Capsule manufactured by M/s Sami Pharmaceuticals Pvt Ltd in three dissolution media. The similarity factor is in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road. (DML No. 000806) (Semi-basic)		
API Lot No.	DLP597		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12 (Months)		
Batch No.	DX60-TR001	DX60-TR002	DX60-TR003
Batch Size	1000 Capsule	1000 Capsule	1000 Capsule

Manufacturing Date		04-2021	04-2021	04-2021
Date of Initiation		24-05-2021	27-05-2021	28-05-2021
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Drug Regulatory Authority of Pakistan renewed w.e.f 02-12-2019 and copy of GMP Certificate (No. F. 3-26/2019-Addl. Dir. (QA & LT-I)-22 dated 25-03-2022. The certificate specifies that the firm was operating at satisfactory level of GMP compliance till 09-05-2022.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable as the API is procured locally.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system. Audit trail report for product testing is submitted.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Firm has applied for new GMP certificate in DRAP field office vide letter No. PH/LHR/REG/655 dated 01-02-2022 and submitted reminders dated 22-03-22, 20-03-2023 and 26-03-2023.
2.	**3.2.S.4.4**	Dissolution testing and Impurity testing of drug substance shall be done by Drug Product manufacturer.	CoA by Drug Product manufacturer stating results of Dissolution testing and Impurity testing of drug substance is submitted.
3.	**3.2.P.2.2.1**	Applicant has submitted results of pharmaceutical equivalence of three parameters only. Complete pharmaceutical equivalence shall be submitted which includes all parameters of finished product given in 3.2.P.5.1 i.e description, weight variation, identification, and tests for impurities/related substances.	Updated pharmaceutical equivalence report submitted.
4.	**3.2.P.8**	Stability studies were initiated more than 20 days after the manufacturing of the batch. Justify.	The stated gap between the manufacturing date and of stability starting date was due to time and availability

				constraint in testing, blistering and packaging processes. Applicant has submitted undertaking that they shall continue stability studies for two years from the date of initiation.	

Decision: Approved with Innovator's Specifications.

- **Applicant shall submit PKR 7500/- pre-registration variation fee prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 for change in specifications from In-house to innovator's specifications,**
- **Applicant shall submit GMP inspection report/ GMP certificate of the manufacturing unit issued by DRAP within the last three years at the time of issuance of registration letter.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Decision of 333rd meeting: - The Board decided to rectify the minutes of 331st meeting of the Registration Board held on 31st October -02nd November, 2023 and consider the strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit as follows in the instant case:

"Each capsule contains:
Dexlansoprazole dual delayed release pellets 22.5% equivalent to Dexlansoprazole…….60mg".

Agenda of Evaluator PEC-XIII.

Case No. 01; Registration applications of locally manufactured Human cases of new License/new sections on form 5F.

CLB in its 278th meeting held on 10th and 11th December 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five (05) sections to M/s Fortune Pharma Private Limited		
505.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 23986, dated 02/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 401648091719 dated: 12/09/2023.
	The proposed proprietary name / brand name	**Levocin 250mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin hemihydrate eq. to levofloxacin ..… 250mg
	Pharmacotherapeutic Group of (API)	J01MA Fluoroquinolones.
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Levofloxacin 250 mg film-coated tablets, MHRA Approved.
	For generic drugs (me-too status)	Lovenox Tablets 250mg, Don Valley, Reg. No. 069370.
	Name and address of API manufacturer.	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. DC-004-2007009, Mfg. date 11-07-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: DC-004-1512001, DC-004-1512002 & DC-004-1512003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator brand i.e. Levaquin 250mg tablets by performing quality tests identification, weight variation, uniformity of dosage unit, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Levaquin 250mg tablets in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). values of F_2 are within the acceptable range.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu-Alu Blister with leaflet packed in a unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	13-12-2021	14-12-2021	15-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. AH20150265) dated 23-12-2020 issued by China Foods & drugs Administration. The certificate specifies that the firm complies with the requirements of Chinese Good Manufacturing Practices for pharmaceutical products. Valid till 22-12-2025. Online verification confirms the validity till 22-12-2020 and the status is "Expired".
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TSN0882021 dated 26-10-2021 mentioning 4kg of levofloxacin hemihydrate USP with B. No. DC-004-2007009, Mfg. date 11-07-2020 attested Assistant Director (I&E) DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 attested by Assistant Director (I&E) DRAP, Karachi dated 09-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	1.6.5	Justification shall be submitted regarding the submitted GMP certificate for drug substance manufacturer as online database of NMPA shows it for M/s Anhui Fengyuan Likang Pharmaceutical Co., Ltd., Bengbu High-tech Development Zone, China instead of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., China. Valid copy of GMP certificate for the drug substance manufacturer issued by relevant/concerned authority shall be submitted as the submitted GMP certificate is expired and validity is till 22-12-2020 in the online database of NMPA.	
4.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.		Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Accelerated stability studies for batch No. DC-004-1512001 of the drug substance shall be submitted.	
7.	3.2.P.2.2	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted. • Justification shall be submitted regarding the submitted results of CDP for Levaquin 500mg and Levaquin 250mg as they are completely same in pH 1.2 and 4.5 mediums.	
8.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

506.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23987, dated 02/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 17271517116 dated: 12/09/2023.
	The proposed proprietary name / brand name	**Levocin 500mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin hemihydrate eq. to levofloxacin ..… 500mg
	Pharmacotherapeutic Group of (API)	J01MA Fluoroquinolones.
	Pharmaceutical form of applied drug	Film Coated Tablet
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Levofloxacin 500 mg film-coated tablets, MHRA Approved.
	For generic drugs (me-too status)	Lovenox Tablets 50mg, M/s Don Valley, Reg. No. 069371.
	Name and address of API manufacturer.	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. DC-004-2007009, Mfg. date 11-07-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: DC-004-1512001, DC-004-1512002 & DC-004-1512003.

	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator brand i.e. Levaquin 500mg tablets by performing quality tests identification, weight variation, uniformity of dosage unit, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Levaquin 250mg tablets in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). values of F_2 are within the acceptable range.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd. Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu-Alu Blister with leaflet packed in a unit Carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	13-12-2021	14-12-2021	15-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. AH20150265) dated 23-12-2020 issued by China Foods & drugs Administration. The certificate specifies that the firm complies with the requirements of Chinese Good Manufacturing Practices for pharmaceutical products. Valid till 22-12-2025. Online verification confirms the validity till 22-12-2020 and the status is "Expired".
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TSN0882021 dated 26-10-2021 mentioning 4kg of levofloxacin hemihydrate USP with B. No. DC-004-

		2007009, Mfg. date 11-07-2020 attested Assistant Director (I&E) DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 attested by Assistant Director (I&E) DRAP, Karachi dated 09-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	1.6.5	Justification shall be submitted regarding the submitted GMP certificate for drug substance manufacturer as online database of NMPA shows it for M/s Anhui Fengyuan Likang Pharmaceutical Co., Ltd., Bengbu High-tech Development Zone, China instead of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., China. Valid copy of GMP certificate for the drug substance manufacturer issued by relevant/concerned authority shall be submitted as the submitted GMP certificate is expired and validity is till 22-12-2020 in the online database of NMPA.	
4.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.		Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Accelerated stability studies for batch No. DC-004-1512001 of the drug substance shall be submitted.	
7.	3.2.P.2.2	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted. • Justification shall be submitted regarding the submitted results of CDP for Levaquin 500mg and Levaquin 250mg as they are completely same in pH 1.2 and 4.5 mediums.	
8.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

507.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26382, dated 01/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 60305514498 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Itrazole 100mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Itraconazole as IR pellets..... 100mg
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	4's or As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Sporanox 100mg capsule, MHRA approved.
	For generic drugs (me-too status)	Rolac 100mg Capsules, Sami Pharmaceuticals, Reg. No. 024491.
	Name and address of API manufacturer.	M/s Surge Laboratories (Pvt.) Ltd., 10th Km Faisalabad Road, Bikhi, District Sheikhupura – Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. ITV-22-001, Mfg. date 10-2020) and justification of specification, reference

		standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Batches: ITC-22-IR-051, ITC-22-IR-053 & ITC-22-IR-054.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Sporanox Capsule by performing quality tests identification, weight variation, uniformity of dosage units, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Sporanox Capsule in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F_2 values calculated are in acceptable renge.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Surge Laboratories (Pvt.) Ltd., 10th Km Faisalabad Road, Bikhi, District Sheikhupura – Pakistan.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	White to off-white spherical IR pellets filled in hard gelatin capsule, blistered in Alu-Alu and further packed in bleach card units.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	15/01/2022	16/01/2022	17/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 182/2019-DRAP (AD-823166-158) dated 04-07-2019 issued on the basis of inspection conducted on 03-07-2019 is submitted by the firm.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	3.2.S.7	Stability studies of the drug substance from drug substance manufacturer shall be submitted.	
4.	2.3	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.	3.2.P.2.2	• Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted. • Details of the innovator product including name of the manufacturer, batch number, manufacturing date, expiry date etc. shall be submitted.	
6.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

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

508.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Sterile liquid injection ampoule SVP (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.25885, dated 26/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 021933578 dated: 15/09/2023.
	The proposed proprietary name / brand name	**Ketrol 10mg/ml injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Ketorolac Tromethamine… 10mg
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drug (NSAID).
	Pharmaceutical form of applied drug	Solution for injection.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	1ml x 5's OR As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ketorolac Trometamol 10 mg/ml solution for injection, MHRA approved.
	For generic drugs (me-too status)	Toradol 10mg/ml (IV/IM), Martin Dow, Reg. No. 014908.
	Name and address of API manufacturer.	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. KM-0302021, Mfg. date 03-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months. Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batches: KM-1102215, KM-1102315 & KM-1102415.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development,

		manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Toradol injection by performing quality tests identification, volume variation, pH, Particulate matter, Assay, Bacterial endotoxin and Sterility.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Type I clear glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	K004	K005	K006
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	16/01/2022	17/01/2022	18/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License (No. 106490/TS/2023) dated 11-03-2023 issued by Drugs Control Administration, Telangana, India. The certificate specifies that the firm is following Good manufacturing practices as stipulated under the provision of Schedule "M" of the Drugs and cosmetics Rules, 1945. Certificate is valid till 09-03-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TWE/CIB.I/20-21 dated 09-11-2021 mentioning 0.2Kg of Ketorolac Tromethamine with B. No. KM-0302021, manufacturing date of 03-2021 attested by Assistant Director, I&E, DRAP Karachi dated 23-11-2021. Firm has also submitted attested copy of Form 6.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	2.3.	• Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted. • Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
3.	3.2.P.1.1	Qualitative composition of the applied formulation is changed from the innovator product in regard of Ethanol and hydrochloric acid as innovator contain both of the above mentioned while applied formulation has not. Justification shall be submitted.	
4.	3.2.P.2.2	• Details of the innovator product against which pharmaceutical equivalence is performed including Manufacturer, batch number manufacturing & expiry date etc. shall be submitted. • Pictorial evidence of the innovator with visible details shall be submitted.	
5.	3.2.P.2.6	This section has mentioned that all the excipients are similar to that of the innovator. However, excipients used are different from innovator and compatibility studies are also not performed. Justification shall be submitted.	
6.	3.2.P.3.3	Justification shall be submitted for terminal sterilization of the applied formulation.	
7.	3.2.P.5.2	Analytical method for assay test has mentioned that transfer 0.83ml of solution which is equivalent to 25mg of ketorolac Tromethamine. Justification shall be submitted that how 0.83 ml will contain 25mg of ketorolac Tromethamine while 1ml of ampoule contains 10mg.	
8.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

509.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Sterile liquid injection ampoule SVP (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.25886, dated 26/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 3185831822 dated: 15/09/2023.
	The proposed proprietary name / brand name	**Ketrol 30mg/ml injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Ketorolac Tromethamine… 30mg
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drug (NSAID).
	Pharmaceutical form of applied drug	Solution for injection.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	1ml x 5's OR As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ketorolac Trometamol 30 mg/ml solution for injection, MHRA approved.
	For generic drugs (me-too status)	Racmic Injection, Neutro Pharma, Reg. No. 068025.
	Name and address of API manufacturer.	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. KM-0302021, Mfg. date 03-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months. Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batches: KM-1102215, KM-1102315 & KM-1102415.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and

		process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Toradol injection by performing quality tests identification, volume variation, pH, Particulate matter, Assay, Bacterial endotoxin and Sterility.
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Perkin Laboratories, Plot No. 94, TSIIC, Medchal Industrial Area, Medchal Village, Medchal Mandal, Medchal-Malkajgiri District Telangana State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Type I clear glass ampoule.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	K001	K002	K003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	16/01/2022	17/01/2022	18/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License (No. 106490/TS/2023) dated 11-03-2023 issued by Drugs Control Administration, Telangana, India. The certificate specifies that the firm is following Good manufacturing practices as stipulated under the provision of Schedule "M" of the Drugs and cosmetics Rules, 1945. Certificate is valid till 09-03-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TWE/CIB.I/20-21 dated 09-11-2021 mentioning 0.2Kg of Ketorolac Tromethamine with B. No. KM-0302021, manufacturing date of 03-2021 attested by Assistant Director, I&E, DRAP Karachi dated 23-11-2021. Firm has also submitted attested copy of Form 6.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	2.3.	• Table for literature references with correct information regarding the drug substance with applicable fee shall be submitted. • Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
3.	3.2.P.1.1	Qualitative composition of the applied formulation is changed from the innovator product in regard of Ethanol and hydrochloric acid as innovator contain both of the above mentioned while applied formulation has not. Justification shall be submitted.	
4.	3.2.P.2.2	• Details of the innovator product against which pharmaceutical equivalence is performed including Manufacturer, batch number manufacturing & expiry date etc. shall be submitted. • Pictorial evidence of the innovator with visible details shall be submitted.	
5.	3.2.P.2.6	This section has mentioned that all the excipients are similar to that of the innovator. However, excipients used are different from innovator and compatibility studies are also not performed. Justification shall be submitted.	
6.	3.2.P.3.3	Justification shall be submitted for terminal sterilization of the applied formulation.	
7.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

510.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.17331, dated 11/07/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 0843732876 dated: 15/08/2022.
	The proposed proprietary name / brand name	**Asthma-F Tablet 10mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Montelukast as sodium 10mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists.
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Singulair 10mg tablets, USFDA approved.
	For generic drugs (me-too status)	Montair 10mg tablets, CCL Pharmaceuticals, Reg. No. 029952.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Masukhana, Parwanoo Distt. Solan [H.P.] India. Copy of GMP certificate No. HFW-H (Drugs) 93/91 issued by State Drugs Controller in the name of M/s Morepen Laboratories Limited, valid till 31-12-2026 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. MS/2107003, Mfg. date 07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C / 65% RH for 24 months Accelerated: 40°C / 75% RH for 6 months Batches: MTN14-8015, MTN14-9001 & MTN14-9036
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis,

		justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Singulair tablets, B. No. 112472, Exp. date 06-2024 manufactured by M/s Merck Research Laboratories by performing quality tests content uniformity, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Singulair tablets in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Morepen Laboratories Limited, Village Masukhana, Parwanoo Distt. Solan [H.P.] India.		
API Lot No.	MS/2107003.		
Description of Pack (Container closure system)	Alu-Alu Blister with leaflet packed in a unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	AF-001	AF-002	AF-003
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	01/2022	01/2022	01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HFW-H (Drugs) 93/91 issued by State Drugs Controller in the name of M/s Morepen Laboratories Limited, valid till 31-12-2026 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a clearance certificate. However, it is not in readable form.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of	Submitted

	stability chambers (real time and accelerated)	

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Justification shall be submitted regarding the analytical method from drug substance manufacturer as all the parameters including flow rate, injection volume, wave length diluent, standard preparation, sample preparation etc. are completely different from USP monograph.	
6.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.P.2.2	Calculations and values of F_2 for all the three mediums shall be submitted.	
8.	3.2.P.8	Clear and readable documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

511.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18307, dated 20/07/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 773720227775 dated: 04/07/2023.
	The proposed proprietary name / brand name	**Newgab capsule 50mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin… 50mg

	Pharmacotherapeutic Group of (API)	Anticonvulsant.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lyrica 50mg capsule, USFDA approved.
	For generic drugs (me-too status)	Medirica 50mg Capsule, Mediate Pharmaceutical, Reg. No. 074971.
	Name and address of API manufacturer.	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Distt. Surat, Gujrat State, India. Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. PG213041, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: Accelerated: 40°C / 75% RH for 6 months Batches: PG120001, PG120002 & PG120003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Lyrica 50 mg with batch No. LR12547, expiry date 11-2024 manufactured by M/s Pfizer by performing quality tests average weight, content uniformity, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lyrica 50 mg with batch No. LC1254,

		expiry date 11-2023 manufactured by M/s Pfizer in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both reference and applied formulations have shown more than 85% release within 15 minutes.		
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.		
STABILITY STUDY DATA				
Manufacturer of API		M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Dist. Surat, Gujrat State, India.		
API Lot No.		PG213041.		
Description of Pack (Container closure system)		1 x 7's capsules in Alu-Alu Blister further packed in bleach card board unit Carton with leaflet.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.		NG-001	AF-002	
Batch Size		5000 Capsules	5000 Capsules	
Manufacturing Date		05/2022	05/2022	
Date of Initiation		11/05/2022	11/05/2022	
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Remarks of evaluator:				

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	1.5.15 to 1.5.20	All commitments shall be submitted.	
4.	2.3	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.7	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.	
7.	3.2.P.2.2	Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.	
8.	3.2.P.8	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

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

512.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.27249, dated 20/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 5050548001 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Newgab 75mg capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin… 75mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specification.
	Proposed Pack size	As per SRO.

	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lyrica 75mg capsule, USFDA approved.
	For generic drugs (me-too status)	Medirica 75mg Capsule, Mediate Pharmaceutical, Reg. No. 074977.
	Name and address of API manufacturer.	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Distt. Surat, Gujrat State, India. Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. PG213041, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: Accelerated: 40°C / 75% RH for 6 months Batches: PG120001, PG120002 & PG120003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Lyrica 75 mg with manufactured by M/s Pfizer by performing quality tests identification, weight variation, uniformity of dosage units, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lyrica 75 mg in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both reference and applied formulations and values of F_2 are in acceptable range.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.
STABILITY STUDY DATA		

Manufacturer of API	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Dist. Surat, Gujrat State, India.		
API Lot No.	PG213041.		
Description of Pack (Container closure system)	Capsules in Alu-Alu Blister further packed in bleach card board unit Carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12/2021	12/2021	12/2021
Date of Initiation	20/12/2021	21/12/2021	22/12/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	

	3.	1.5.15 to 1.5.20	All commitments shall be submitted.		
	4.	2.3	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.		
	5.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.		
	6.	3.2.S.7	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.		
	7.	3.2.P.2.2	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.		
	8.	3.2.P.5.1	Dissolution specification provided by the drug product manufacturer has mentioned NLT 80% (Q) in 15 minutes while BP has mentioned time limit of 30minutes. Justification shall be submitted.		
	9.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Injection volume in the submitted chromatograms with respect to the official monograph shall be justified.		

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

513.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.27250, dated 20/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 566988064 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Newgab 100mg capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregabalin… 100mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant.

	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lyrica 100mg capsule, USFDA approved.
	For generic drugs (me-too status)	Medirica 100mg Capsule, Mediate Pharmaceutical, Reg. No. 074972.
	Name and address of API manufacturer.	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Distt. Surat, Gujrat State, India. Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. PG213041, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: Accelerated: 40°C / 75% RH for 6 months Batches: PG120001, PG120002 & PG120003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Lyrica 75 mg with manufactured by M/s Pfizer by performing quality tests identification, weight variation, uniformity of dosage units, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lyrica 75 mg in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all

		the three mediums both reference and applied formulations and values of F_2 are in acceptable range.
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s CTX Lifesciences (Pvt.) Ltd., Block No. 251/ P, 252/ P, 253 to 255, 256/ P, 258/ P, 276/ P, 277, 278/ P, 279 to 282, 293/ P, 284/ P GIDC, City – Sachin Dist. Surat, Gujrat State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Capsules in Alu-Alu Blister further packed in bleach card board unit Carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12/2021	12/2021	12/2021
Date of Initiation	20/12/2021	21/12/2021	22/12/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 in the name of M/s CTX Lifesciences (Pvt.) Ltd., issued by Food & Drugs Control Administration, Gujrat State, India valid till 29-05-2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021mentioning 1.5kg of Pregabalin with B. No. PG213041, Mfg. date 10-2021 attested by Assistant Director I&E, DRAP, Karachi dated 22-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of evaluator:

Sr. No.	**Section**	**Observation**	**Reply by the firm**

	1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.		
	2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.		
	3.	1.5.15 to 1.5.20	All commitments shall be submitted.		
	4.	2.3	• Table for literature references with correct information regarding the drug product with applicable fee shall be submitted. • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.		
	5.	3.2.S.4.4	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.		
	6.	3.2.S.7	Clear and readable copies of real time stability studies of the drug substance for three batches as per zone Iva shall be submitted.		
	7.	3.2.P.2.2	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number &manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator product with clear information of batch number, manufacturing date, expiry date etc. shall be submitted.		
	8.	3.2.P.5.1	Dissolution specification provided by the drug product manufacturer has mentioned NLT 80% (Q) in 15 minutes while BP has mentioned time limit of 30minutes. Justification shall be submitted.		
	9.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Injection volume in the submitted chromatograms with respect to the official monograph shall be justified.		

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

514.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24323, dated 04/10/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 228659180716 dated: 12/09/2023.

	The proposed proprietary name / brand name	**Ternafine 250mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Terbinafine as Hydrochloride 250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	Oral, Uncoated Tablet
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	10's or As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lamisil 250mg tablet, TGA Australia Approved.
	For generic drugs (me-too status)	Brandit 250mg tablet, High-Q Pharmaceutical, Reg. No. 090823.
	Name and address of API manufacturer.	M/s Saptagir Laboratories (Pvt.) Ltd., Sy. No. Parts of 27, 46 and 50 to 56, Ananthasagar Village, Chegunta Mandal, Medak District, Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. TER04422, Mfg. date 10-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: TH0131216, TH0141216 & TH0151216.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator brand i.e. Lamisil 250mg tablets by performing quality tests identification, weight variation, uniformity of dosage unit, Dissolution & Assay. Comparative Dissolution is also performed against the same brand that is Lamisil 250mg tablets in Acid media (pH

		1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). values of F_2 are within the acceptable range.		
	Analytical method validation/verification of product	Method validation studies are submitted including , specificity, accuracy & precision.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Saptagir Laboratories (Pvt.) Ltd., Sy. No. Parts of 27, 46 and 50 to 56, Ananthasagar Village, Chegunta Mandal, Medak District, Telangana State, India.		
API Lot No.		Not submitted.		
Description of Pack (Container closure system)		Alu-Alu Blister with leaflet packed in a unit Carton.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.		TR004	TR005	TR006
Batch Size		1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date		11-2021	11-2021	11-2021
Date of Initiation		28-11-2021	29-11-2021	30-11-2021
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 82079/TS/2022) dated 22-09-2022 issued by Drug Control Administration, Telangana, India. The certificate specifies that the firm is following Good manufacturing practices as stipulated under the provision of Schedule "M" of the Drugs and cosmetics Rules, 1945. Certificate is valid till 22-09-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EX/RU/031/21-22 dated 25-10-2021 specifying 2.0Kg of Terbinafine Hydrochloride attested by Assistant Director (I&E) DRAP, Karachi dated 22-11-2021. Firm has also submitted copy of form 6 attested by Assistant Director (I&E) DRAP, Karachi dated 22-11-2021.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate for the drug substance manufacturer issued by relevant/concerned authority shall be submitted.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.5	COA and details of the working standard used in the trial batches shall be submitted.	
5.	3.2.P.2.2	• Details of the innovator product used in pharmaceutical equivalence and CDP including manufacturer name, batch number & manufacturing and expiry date shall be submitted. • Pictorial evidence of the innovator pack with visible details shall also be submitted.	
6.	3.2.P.6	COA and details of the working standard used in the trial batches shall be submitted.	
7.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

515.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26385, dated 01/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 8729259911 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Paramol 120mg/5ml Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of suspension contains: Paracetamol 120mg
	Pharmacotherapeutic Group of (API)	Antipyretic/Analgesic.

	Pharmaceutical form of applied drug	Oral suspension.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Calpol Sugar Free Infant Suspension MHRA approved.
	For generic drugs (me-too status)	Paracetamol suspension, Ferozsons laboratories, Reg. No. 001517.
	Name and address of API manufacturer.	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 202109103A, Mfg. date 23-09-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30° ±2°C / 65% ±5% RH for 48 months. Accelerated: 40°C ±2°C / 75% ±5% RH for 6 months Batches: 011608001, 011608002 & 011608001.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol suspension with batch No. 321062, expiry date 08-2022 by performing quality tests (identification, filled volume, pH, uniformity of dosage unit and assay).
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA	
Manufacturer of API	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.
API Lot No.	Not submitted.
Description of Pack	Amber glass bottles 0f 60ml closed with white PP child proof screw caps.

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	18/01/2022	19/01/2022	20/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. HE20160062 issued by State Food and Drug Administration i.e. Hebei Provincial Drug Administration valid for the period of 15-11-2020 to 14-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TM20210315-7600S dated 26-10-2021 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	

	4.	3.2.S.4.4	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.		
	5.		• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.		

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

516.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26386, dated 01/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 244818459 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Paramol 250mg/5ml Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of suspension contains: Paracetamol 250mg
	Pharmacotherapeutic Group of (API)	Antipyretic/Analgesic.
	Pharmaceutical form of applied drug	Oral suspension.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Calpol Six Plus Suspension, MHRA approved.
	For generic drugs (me-too status)	Mismol plus suspension, Mission pharmaceuticals, Reg. No. 080313.
	Name and address of API manufacturer.	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 202109103A, Mfg. date 23-09-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30° ±2°C / 65% ±5% RH for 48 months. Accelerated: 40°C ±2°C / 75% ±5% RH for 6 months Batches: 011608001, 011608002 & 011608001.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol six plus suspension with batch No. 48693, expiry date 08-2022 by performing quality tests (identification, filled volume, pH, uniformity of dosage unit and assay).
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Amber glass bottles 0f 60ml closed with white PP child proof screw caps.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T004	T005	T006
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	18/01/2022	19/01/2022	20/01/2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. HE20160062 issued by State Food and Drug Administration i.e. Hebei Provincial Drug Administration valid for the period of 15-11-2020 to 14-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TM20210315-7600S dated 26-10-2021 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
1.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
2.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
3.	3.2.S.4.4	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	
4.		• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	

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

517.	Name, address of Applicant / Marketing Authorization Holder	**Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.**
	Name, address of Manufacturing site.	Fortune Pharmaceuticals, Plot No. K/201 S.I.T.E., Super Highway, Phase II Karachi.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New license issued on 10-06-2021 w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-3/2016-Lic dated 14/06/2021 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26384, dated 01/11/2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 34443282668 dated: 27/10/2023.
	The proposed proprietary name / brand name	**Paramol 80mg/0.8ml infant drops.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.8ml (one calibrated dropper) of suspension contains: Paracetamol 80mg
	Pharmacotherapeutic Group of (API)	Antipyretic/Analgesic.
	Pharmaceutical form of applied drug	Oral Drops.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	PANADOL CHILDREN 1 MONTH - 1 YEAR paracetamol 100 mg/mL oral liquid bottle, TGA approved.
	For generic drugs (me-too status)	Munapol Infant drops, Munawar Pharma, Reg. No. 067775.
	Name and address of API manufacturer.	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 202109103A, Mfg. date 23-09-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30° ±2°C / 65% ±5% RH for 48 months. Accelerated: 40°C ±2°C / 75% ±5% RH for 6 months Batches: 011608001, 011608002 & 011608001.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Panadol infants drops by GSK with batch No. M35K, expiry date 11-2023 by performing quality tests (identification, filled volume, pH, uniformity of dosage unit and assay).
	Analytical method validation/verification of product	Method verification studies are submitted including , specificity, accuracy & precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Jiheng Pharmaceutical Co., Ltd, 1 Weiwu Street Industrial Park Hengshui City, Hebei Province, China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Amber glass bottles of 30ml packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T007	T008	T009
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	18/01/2022	19/01/2022	20/01/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. HE20160062 issued by State Food and Drug Administration i.e. Hebei Provincial Drug Administration valid for the period of 15-11-2020 to 14-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. TM20210315-7600S dated 26-10-2021 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021. Firm has also submitted copy of Form 6 mentioning 15kg of Paracetamol attested by Assistant Director I&E, DRAP, Karachi dated 18-11-2021.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Name and address on the submitted challan is Fortune pharma (Pvt.) Ltd., Plot 20/K SITE, Super High Way Phase II Karachi While the name and address mentioned on DML is M/s Fortune Pharmaceuticals, Plot No. K/201, S.ITE., Super High Way Phase II Karachi. Justification shall be submitted.	
2.	1.5.4	Proposed pack size for the applied formulation shall be mentioned.	
3.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.4.4	Certificate of Analysis (COA) for the drug substance of the same batch from Drug Substance / API manufacturer and drug product manufacturer shall also be submitted.	
5.		• Stability data sheets as per decision of the Registration Board with inclusion of API lot number shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Submitted chromatograms does not reflect any applied wavelength. Justification shall be submitted. • Submitted chromatograms have mentioned 20µl injection volume while USP has recommended 10 µl. justification shall be submitted.	

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

CLB in its 282nd meeting held on 31st August 2021, has considered and approved the grant of DML by way of Formulation with following 3 sections:
Tablet Section (General)
Capsule Section (General)
Cream/ointment section (General)

518.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 14-09-2021.
	Evidence of approval of manufacturing facility	Cream/Ointment section (general) approved vide No. F 1-7/2012-Lic dated 14-09-2021.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19213; dated 02/08/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No. 705807296314 dated 07/07/2023.
	The proposed proprietary name / brand name	**Axafine 1% w/w cream.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Terbinafine HCl..... 10mg
	Pharmaceutical form of applied drug	Topical Cream.
	Pharmacotherapeutic Group of (API)	Antifungal for topical use.
	Reference to Finished product specifications	JP specifications.
	Proposed Pack size	10gm.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	LAMISIL 1% w/w Cream, MHRA approved.
	For generic drugs (me-too status)	Lamisil 1% cream by GSK OTC, Reg. No. 013210.
	Name and address of API manufacturer.	M/s Shandong Boyuan Pharmaceutical Co. Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed data of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 220203TA, mfg. date, 23-02-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months. Accelerated: 40˚C±2˚C / 75% ± 5% RH for 6 months. Batches: (150401TH, 150402TH & 150403TH)

	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Lamisil Cream manufactured by GSK Pakistan by performing quality tests for minimum fill, microbial limit & assay.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Envee Drugs (Pvt.) Ltd., N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist; Kheda, Gujrat, India.		
API Lot No.	210617WS.		
Description of Pack (Container closure system)	Aluminum tube packed in unit carton with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CR-01	CR-02	CR-03
Batch Size	100 tubes	100 tubes	100 tubes
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	12-2022	12-2022	12-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 No. K-400580286971 mentioning 600 grams of Terbinafine HCl USP attested by Assistant Director I&E, DRAP, Islamabad dated 30-04-2022. Firm has also submitted copy of commercial invoice No. 0109SLT2202801-2 dated 22-02-2022 mentioning 600 grams of Terbinafine HCl USP with Batch No. 211005TA & manufacturing date of 28-08-2021. ***However, submitted batch number is not present inbatch analysis and stability data sheets. Also the invoice***

		is from M/s Zhejiang Top Hankook Biopharm Co. Ltd., Hangzhou China.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Covering letter has mentioned label claim of Terbinafine as HCl 10mg. justification shall be submitted.	Firm has submitted that covering letter contain brand name along with generic name in bracket (Terbinafine HCL) But in next place it is written wrongly, in dossier and fee deposit slip it is correctly written Terbinafine HCl 1%.
2.	1.6.5	Complete information in this section shall be submitted.	Firm has submitted complete details of this section including the names, addresses and vendor qualification of both the drug substances.
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. SD20160496 26-08-2016 in the name of M/s Shandong Boyuan Pharmaceutical Co. Ltd., China issued by CFDA valid till 25-08-2021. Firm has also submitted copy of License No. 20160312 valid till 25-04-2026.
4.	2.3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Submitted.
5.	3.2.S.4.1	Specifications submitted by the drug product manufacturer for drug substance has mentioned assay limits of 98% - 102% with reference of EP and JP. While both EP and JP have assay limits of 99% - 101%. Justification shall be submitted.	Firm has submitted that it was written by mistake and further submitted that results were within the limits of 99% - 101%. They also submitted new corrected COA with limits of 99% - 101%. ***However, fee for pre-registration variation is not submitted.***
6.	3.2.S.4.2	Signed analytical procedures for the drug substance from the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.3	In analytical method verification report, actual concentration correspondent to different	Submitted.

			percentages used in different parameters shall be mentioned and submitted accordingly.		
	8.	3.2.S.4.4	COAs submitted by both drug substance manufacturer and drug product manufacturer have specification as per USP monograph while verification studies provided by the drug product manufacturer are as per JP monograph. Justification shall be submitted.	Firm has submitted that Pharmacopoeia referred is corrected, next we will fellow USP for API if advised by board. Furthermore both compendial parameter/limits are exactly same and verification study result comply both compendia (pharmacopoeia).	
	9.	3.2.P.1	Justify the quantity of Terbinafine HCl i.e. 11.25 mg per gram.	Firm has submitted that this happened due to interchange of row in table 11.25 mg/gm is isopropyl myristate while Terbinafine HCl is 10 mg (1%) but during putting in tabulated template both the adjacent row pasted in reverse order. They also submitted corrected formulation and submitted that further verification can be observed from dispensing sheet of BMR.	
	10.	3.2.P.2	Pharmaceutical development has mentioned 2% of Terbinafine HCl. Clarification shall be submitted.	Firm has submitted that it is 1% instead of 2%. Same Pharmaceuticals development template is used as that of other cream strength. Sometime after changing the word/line remain unsaved and become undo automatically. Same case happened here. We feel regret for it.	
	11.	3.2.P.2.2	Details of the product against which pharmaceutical equivalence is performed including batch number and manufacturing date etc. shall be submitted.	Firm has submitted picture of Lamisil cream, B. No. DJ8D, mfg. date of 08-2022 manufactured by GSK Pakistan.	
	12.	3.2.P.3	This section has mentioned Pearl pharma as manufacturer. Clarification shall be submitted.	Firm has submitted that they generally share or download general/ blank template from google in order to present their data in more precise way, e.g. product development template, then put our details and data in these template. Sometime after changing the word/line remain unsaved and become undo automatically. Same case happened here, and we feel regret for it. correction is made.	
	13.	3.2.P.8	• Pack size of the tube in which stability studies are conducted shall also be mentioned. • Documents for the procurement of API used in the development of trial batches with approval from DRAP (in case of import) shall be submitted.	Firm has submitted that 10gm of tube is used in stability testing. Firm has submitted clearance certificate No. E-1091780282981 dated 13-05-2022 mentioning 600gm of Terbinafine HCl, B. No. 211005TA attested by Assistant Director I&E, DRAP, Islamabad.	

				However, the batch No. in 3.2.S.4.4 is 220203TA while in stability data it is 210617WS.
			• Justification shall be submitted regarding the batch number and manufacturing date of the drug substance as in 3.2.S.4.4 batch number is 220203TA while in stability data it is 210617WS while in commercial invoice it is 211005TA.	Firm has submitted a picture of container for Terbinafine HCl with B. No. 220203TA, mfg. date of 23-02-2022. They further submitted that this container shows the same batch number as that on the COA. The different batch number on the invoice i.e. 211005TAis probably due to indenter/supplier/exporter typographic mistake. ***However, clearance certificate No. E-1091780282981 dated 13-05-2022 mentioning 600gm of Terbinafine HCl, has also mentioned B. No. 211005TA.***
			• Raw data sheets for calculation of assay test at each time point for both accelerated as well as real time shall be submitted.	Submitted.
			• Justification shall be submitted for not performing system suitability studies.	Firm has submitted that %RSD has been calculated at each test interval. However, Specific system suitability test standard solution containing internal standard has been prepared and used at 09th month interval. Chromatograms are submitted.
			• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that we are new DML so it is not applicable.

Decision: Deferred for following;

- **Submission of fee of 30,000/- for pre-approval correction/change in registration application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Clarification regarding the API lot number shall be submitted as in section 3.2.S.4.4 it is 220203TA, while in stability data sheets of the product it is 210617WS and in the clearance certificate of drug substance it is 211005TA.**

519.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 14-09-2021.
	Evidence of approval of manufacturing facility	Cream/Ointment section (general) approved vide No. F 1-7/2012-Lic dated 14-09-2021.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 19992; dated 11/08/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No. 66507898335 dated 07/07/2023.
	The proposed proprietary name / brand name	**Furiclar H- Craem.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Hydrocortisone acetate ..... 10mg Fusidic Acid… 20mg
	Pharmaceutical form of applied drug	Topical Cream.
	Pharmacotherapeutic Group of (API)	Antibiotic and corticosteroid for topical use.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	5gm and 15gm.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Fucidin H Cream, by Leo Laboratories, MHRA approved.
	For generic drugs (me-too status)	Fusimax-H 2% Cream, Maxitech pharma, Reg. No. 083733.
	Name and address of API manufacturer.	**Fusidic Acid;** Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anquing Anhui China. **Hydrocortisone acetate;** Tianjin Jinjin Pharmaceutical Co., Ltd., No. 8 of Jingfu Road, Industrial zone of Zhangjiawo Town, Xiqing District, Tianjin China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Fusidic Acid;** Firm has submitted detailed data of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 21120901, mfg. date, 09-12-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Hydrocortisone acetate;** Firm has submitted detailed data of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. HD0088, mfg. date, 16-10-2021) and justification

		of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	**Fusidic Acid:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months. Batches: (20181001, 20181016 & 20181101) **Hydrocortisone acetate:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months. Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months. Batches: (Cjd-191101, Cjd-191102 & Cjd-191103)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Fucidin Cream manufactured by LEO by performing quality tests (identification, minimum fill weight, assay & microbial count).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Fusidic Acid:** Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anquing Anhui China. **Hydrocortisone acetate:** Tianjin Jinjin Pharmaceutical Co., Ltd., No. 8 of Jingfu Road, Industrial zone of Zhangjiawo Town, Xiqing District, Tianjin China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Aluminum tube packed in unit carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CR-01	CR-02	CR-03
Batch Size	200 tubes	200 tubes	200 tubes
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation			
No. of Batches	03		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION			
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.			
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Fusidic Acid:** Firm has submitted copy of Form-6 N0. K-54180289532 mentioning 500 grams of Fusidic Acid EP attested by Assistant Director I&E, DRAP, Islamabad dated 12-04-2022. Firm has also submitted copy of commercial invoice No. WD202201040 dated 03-01-2022 mentioning 500 grams of Fusidic Acid EP with B. No. 21120901, mfg. date, 09-12-2021. However, invoice is not attested by DRAP. **Hydrocortisone acetate:** Firm has submitted copy of Form-6 N0. K-32480284268 mentioning 130 grams of Hydrocortisone acetate USP attested by Assistant Director I&E, DRAP, Islamabad dated 07-02-2022. Firm has also submitted copy of commercial invoice No. 22HA-009 dated 24-01-2022 mentioning 130 grams of Hydrocortisone acetate USP with B. No. HD0088, mfg. date, 16-10-2021. However, invoice is not attested by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Complete information in this section shall be submitted.	Firm has submitted complete details of this section including the names, addresses and vendor qualification of both the drug substances.
2.	1.6.5	Valid copy of GMP certificate of both the drug substance manufacturers shall be submitted.	**Hydrocortisone acetate:** Firm has submitted copy of GMP certificate No. TJ20180174 issued to M/s Tianjin Jinjin Pharmaceutical Co., Ltd., issued by CFDA dated 24-12-2018 valid till 23-12-2023. Firm has also submitted copy of Lic. No. Jin 20150040 valid till 23-11-2025. **Fusidic Acid:** Firm has submitted copy of License no. 20190399 valid till 31-12-2025.
3.	2.3.R	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug	Submitted.

		product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	3.2.S.4.2	Signed analytical procedures for both the drug substances from the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	In analytical method verification report of both the drug substances, actual concentration correspondent to different percentages used in different parameters shall be mentioned and submitted accordingly.	Submitted.
6.	3.2.S.5	Details and COA of the reference standard/working standard used for both the drug substances shall be submitted.	Firm has submitted COAs of the working standards for both the drug substances.
7.	3.2.S.7	Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets of Fusidic acid.	Firm has submitted new stability data sheets from manufacturer for the 03 batches of the drug substance both at real time and accelerated condition.
8.	3.2.P.2.2	• Details of the product against which pharmaceutical equivalence is performed including batch number and manufacturing date etc. shall be submitted. • Justification shall be submitted for not performing pharmaceutical equivalence against the same formulation as it is performed against Fucidin cream. • Assay results of the pharmaceutical equivalence is for one drug substance and that one substance is also not mentioned. Justification shall be submitted.	Firm has submitted new pharmaceutical equivalence against Melas H cream, Batch No. MS005H, mfg. date 09-2022 manufactured by Atco laboratories by performing quality tests (identification, minimum fill weight, assay & microbial count). Firm has submitted that pharmaceuticals equivalence against same formulation (Fucidin H) was performed mentioning both the API in assay limit but due to 5 times return of these dossier from screening desk, we have make frequent changes by opening the whole dossier, it may have happened that in place of Fucidin H cream formulation, simple Fucidin Cream containing page inserted may be placed in the dossier by mistake. Correction is made.
9.	3.2.P.5.1	Specifications has mentioned pH "where applicable". Justification shall be submitted for not providing any specification i.e. value for pH of the formulation.	Firm has submitted that since it is a non-compendial product, we searched for the innovator product. However, pH limits could not be found in innovator/reference product.
10.	3.2.P.5.3	Complete method verification studies for drug product with actual concentration correspondent to different percentages used in different parameters shall be mentioned and submitted accordingly.	Submitted.
11.	3.2.P.5.6	Justification of specifications has mentioned BP specifications. Clarification shall be submitted.	Firm has submitted that it was a typographic error. They also provided new justifications for specifications.
12.	3.2.P.6	Details and COA of the reference standard/working standard used for both the drug substances shall be submitted.	Submitted.
13.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number, batch quantity and starting date shall be submitted.	Firm has submitted new stability data sheets mentioning API lot numbers for Hydrocortisone acetate (HD0088) & Fusidic acid (21120901) and batch size of 200 tubes.

		• Pack size of the tube in which stability studies are conducted shall also be mentioned. • Documents for the procurement of API used in the development of trial batches with approval from DRAP (in case of import) shall be submitted. • Justify the value of hydrocortisone acetate in the submitted raw data sheets for calculation of assay with respect to the submitted analytical procedures. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted that 15gm of tube is used in stability testing. Firm has submitted copy of Form 6 No. K-32480284268 dated 07-02-2022 mentioning 130gm of Hydrocortisone acetate attested by Assistant Director, I&E, DRAP, Islamabad. Firm has also submitted copy of Form 6 No. K-54180289532 dated 12-04-2022 mentioning 500gm of Fusidic acid attested by Assistant Director, I&E, DRAP, Islamabad. Firm has also submitted clearance certificate No. E-877780288753 mentioning 500gm of Fusidic acid, B. No. 21120901 attested by Assistant Director, I&E, DRAP, Islamabad. Firm has submitted that in analytical procedures it was mistakenly written as 0.2mg/ml. Actually it is 0.1mg/ml and method verification also contains 0.1mg/ml. they further also provided calculation sheets. ***However, fee for pre-registration variation is not submitted by the firm*** Submitted. Firm has submitted that we are new DML so it is not applicable.

Decision: Approved. Registration letter will be issued after submission of fee of 30,000/- for pre-approval correction/change in registration application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

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

520.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 14-09-2021.
	Evidence of approval of manufacturing facility	Cream/Ointment section (general) approved vide No. F 1-7/2012-Lic dated 14-09-2021.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18243; dated 19/07/2023.

	Details of fee submitted	PKR 30,000/-: vide slip No. 782904641649 dated 07/07/2023.
	The proposed proprietary name / brand name	**Furicular 2% w/w Cream.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Fusidic Acid… 20mg
	Pharmaceutical form of applied drug	Topical Cream.
	Pharmacotherapeutic Group of (API)	Antibiotic for topical use.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	5gm and 15gm.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Fucidin 20 mg/g Cream, MHRA approved.
	For generic drugs (me-too status)	Fudic Cream 2%, Shaigan pharmaceuticals, Reg. No. 025938.
	Name and address of API manufacturer.	Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anquing Anhui China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Fusidic acid present in BP. Firm has submitted detailed data of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 21120901, mfg. date, 09-12-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months. Batches: (20181001, 20181016 & 20181101)
	Module-III (Drug Product):	Official monograph of the applied formulation is present in USP. Firm has submitted detail of the drug product including its description, composition, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Fucidin Cream manufactured by LEO by performing quality tests (identification, pH, minimum fill weight, assay & microbial count).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng West Road Anquing Anhui China.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Aluminum tube packed in unit carton with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CR-01	CR-02	CR-03
Batch Size	200 tubes	200 tubes	200 tubes
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation			
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form-6 N0. K-54180289532 mentioning 500 grams of Fusidic Acid EP attested by Assistant Director I&E, DRAP, Islamabad dated 12-04-2022. Firm has also submitted copy of commercial invoice No. WD202201040 dated 03-01-2022 mentioning 500 grams of Fusidic Acid EP with B. No. 21120901, mfg. date, 09-12-2021. However, invoice is not attested by DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted

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

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	Fee slip submitted has mentioned Fusidic acid 10mg while the application is for 20mg. justification shall be submitted.	Firm has submitted that 10mg is written wrongly by accountant and on covering letter and dossier it is correctly written as 20mg or 2%.
2.	1.6.5	Complete information in this section shall be submitted.	Firm has submitted complete details of this section including the names, addresses and vendor qualification of both the drug substances.
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of License no. 20190399 valid till 31-12-2025.
4.	2.3.R	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Submitted.
5.	3.2.S.4.2	Signed analytical procedures for the drug substance from the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	In analytical method verification report, actual concentration correspondent to different percentages used in different parameters shall be mentioned and submitted accordingly.	Submitted.
7.	3.2.S.5	• Details and COA of the reference standard/working standard used shall be submitted.	Submitted.
8.	3.2.S.7	• Justification shall be submitted for over writing the real time stability conditions in the submitted stability data sheets.	Firm has submitted new stability data sheets from manufacturer for the 03 batches of the drug substance both at real time and accelerated condition.
9.	3.2.P.2.2	Details of the product against which pharmaceutical equivalence is performed including batch number and manufacturing date etc. shall besubmitted.	Firm has submitted new pharmaceutical equivalence against Melas cream, Batch No. MS005H, mfg. date 09-2022 manufactured by Atco laboratories by performing quality tests (identification, minimum fill weight, assay & microbial count).
10.	3.2.P.5.2	Signed analytical procedures for the drug substance from the drug product manufacturer shall be submitted.	Submitted.
11.	3.2.P.5.2	Complete method verification studies for drug product with actual concentration correspondent to different percentages used in different parameters shall be mentioned and submitted accordingly.	Submitted.
12.	3.2.P.6	• Details and COA of the reference standard/working standard used shall be submitted.	Submitted.
13.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of	Firm has submitted new stability data sheets mentioning API lot numbers for Fusidic acid (21120901) and batch size of 200 tubes.

		API lot number, batch quantity and starting date shall be submitted. • Pack size of the tube in which stability studies are conducted shall also be mentioned. • Documents for the procurement of API used in the development of trial batches with approval from DRAP (in case of import) shall be submitted. • Raw data sheets for calculation of assay test at each time point for both accelerated as well as real time shall be submitted as per USP monograph. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted that 15gm of tube is used in stability testing. Firm has submitted copy of Form 6 No. K-54180289532 dated 12-04-2022 mentioning 500gm of Fusidic acid attested by Assistant Director, I&E, DRAP, Islamabad. They have also submitted clearance certificate No. E-877780288753 dated 18-04-2023. Submitted. Submitted. Firm has submitted that we are new DML so it is not applicable.

Decision: Approved. Registration letter will be issued after submission of fee of 30,000/- for pre-approval correction/change in the applied formulation i.e. 20mg instead of 10mg as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

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

521.	Name, address of Applicant / Marketing Authorization Holder	**M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License issued on 14-09-2021.
	Evidence of approval of manufacturing facility	Cream/Ointment section (general) approved vide No. F 1-7/2012-Lic dated 14-09-2021.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19991; dated 11/08/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No. 20518713 dated 09/08/2023.
	The proposed proprietary name / brand name	**Visone 0.1% Cream.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Betamethasone as valerate..... 1mg
	Pharmaceutical form of applied drug	Topical Cream.

	Pharmacotherapeutic Group of (API)	Corticosteroid.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	5gm and 15gm.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Betamethasone valerate eq. to 0.1% base, USFDA approved.
	For generic drugs (me-too status)	Betnovate cream, GSK Pakistan, Reg. No. 000256.
	Name and address of API manufacturer.	M/s Envee Drugs (Pvt.) Ltd., N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist; Kheda, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Betamethasone valerate is present in USP. Firm has submitted detailed data of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. EV/BV-439/21, mfg. date, 23-02-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months. Accelerated: 40˚C±2˚C / 75% ± 5% RH for 6 months. Batches: (EV/00808, EV/06308 & EV/10507)
	Module-III (Drug Product):	Official monograph of the applied formulation is present in USP. Firm has submitted detail of the drug product including its description, composition, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Betnovate Cream manufactured by GSK Pakistan by performing quality tests for assay only.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Envee Drugs (Pvt.) Ltd., N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist; Kheda, Gujrat, India.
API Lot No.	Not submitted.

Description of Pack (Container closure system)	Aluminum tube packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CR-01	CR-02	CR-03
Batch Size	200 tubes	200 tubes	200 tubes
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation			
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-535080283149 mentioning 35 grams of Betamethasone Valerate USP with Batch No. EV/BV-257/21, manufacturing date of 06-11-2021 attested by Assistant Director I&E, DRAP, Islamabad dated 31-03-2021. ***However, in 3.2.S.4.4 batch number of the drug substance mentioned is B. No. EV/BV-439/21, mfg. date, 23-02-2022.***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Complete information in this section shall be submitted.	Firm has submitted complete details of this section including the names, addresses and vendor qualification of the drug substance.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/21072790 valid from 07-07-2021 to 06-07-2023.

			Firm has also submitted copy of renewal of license to manufacture till 25-02-2023. ***Both GMP certificate and License are not valid.***
3.	2.3.R	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Submitted.
4.	3.2.S.4.2	Signed analytical procedures for the drug substance from the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	• In analytical method verificationreport, actual concentration correspondent to different percentagesused in different parameters shall be mentioned and submitted accordingly. • Analytical method verification report for both drug substance and drug product have same results. Analytical record for both the drug substance and drug product shall be submitted.	Submitted.
6.	3.2.P.2.2	• Details of the product against which pharmaceutical equivalence is performed including batch number and manufacturing date etc. shall be submitted. • Justification shall be submitted for performing only assay test in pharmaceutical equivalence studies.	Firm has submitted that complete testing of pharmaceutical equivalence was submitted in Module 2 by mistake. They now once again submitted PE studies against Betnovate Cream, Batch No. 4F3G, mfg. date 06-2023 manufactured by M/s GSK Pakistan by performing description, identification, assay, microbial count etc.
7.	3.2.P.5.2	Signed analytical procedures for the drug substance from the drug product manufacturer shall be submitted.	Submitted.
8.	3.2.P.8	• Stability data sheets as per decision of the Registration Board with inclusion of API lot number, batch quantity and starting date shall be submitted. • Pack size of the tube in which stability studies are conducted shall also be mentioned. • Documents for the procurement of API used in the development of trial batches with approval from DRAP (in case of import) shall be submitted. • Submitted chromatograms does not reflect any wave length. Justification shall be submitted. • Submitted chromatograms have also mentioned 1% cream. Justification shall be submitted. • Justification shall be submitted regarding the injection volume as USP has mentioned 100µl while the	Firm has submitted new stability data sheets mentioning API lot numbers for Betamethasone (EV/BV-439/21) and batch size of 200 tubes. Firm has submitted that 10gm of tube is used in stability testing. Firm has submitted copy of For-6 No. K-217880286824 dated 18-03-2022 mentioning betamethasone valerate USP from Envee Drugs pvt. Ltd., India attested by Assistant Director I&E, DRAP, Islamabad. Firm has submitted that they perform studies on Perkin elmer HPLC Software which by default did not print the given wavelength. Now we have changed it to water HPLC (Empower software) and also submitted one time chromatograms. Firm has submitted that we named the folder 1% that is why 1% also appears in the chromatograms. They further submitted that chromatograms also mentioned visone cream 0.1% several times. Firm has submitted that we followed USP 29 which mentioned inj. Volume of 10µl.

		submitted chromatograms have used 10 µl. • Raw data sheets for calculation of assay test at each time point for both accelerated as well as real time shall be submitted as per USP monograph. • Justification shall be submitted for not performing system suitability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted. Firm has submitted that they followed USP 29 monograph, where system suitability is not mentioned. But still they have performed %RSD which can be seen in the calculation sheets. They further submitted that now they perform SST according to USP 43 and in all the remaining time points they will perform analysis as per USP43. Firm has submitted that we are new DML so it is not applicable.
Decision: Deferred for following; • **Submission of valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority.** • **Clarification regarding the API lot number shall be submitted as in section 3.2.S.4.4 and 3.2.P.8 (Stability data sheets) it is B. No. EV/BV-439/21, mfg. date, 23-02-2022, while in the clearance certificate of drug substance it is EV/BV-257/21 with manufacturing date of 06-11-2021.**		

Case No. 02; Registration applications of locally manufactured Human cases of contract manufacturing on form 5F.

522.	Name, address of Applicant / Marketing Authorization Holder	**M/s Onyx Pharmaceuticals, 30-A, Industrial Estate, Mansehra.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Onyx Pharmaceuticals:** Not submitted. **M/s Bio-Labs (Pvt.) Ltd.,** Not submitted.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 1-12/89-Lic (Vol-II) dated 23-07-2012 mentioning ampoule (general) section is submitted by the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1731; dated 18-01-2023.
	Details of fee submitted	PKR 75,000/-: vide slip No. 0288763521 dated 15-11-2022.
	The proposed proprietary name / brand name	**Ketonex 30mg Injection.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ketorolac Tromethamine 30mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoule
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1ml x 5's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	US FDA approved.
	For generic drugs (me-too status)	Tekac 30mg/ml Injection, Sami Pharmaceuticals, Reg. No. 092855.
	Name and address of API manufacturer.	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. **Manufacturing site address:** M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. KTM180021, Mfg. date 15-08-18) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 ^{O} ± 2 ^{O} C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2 ^{O} C / 65% ± 5% RH for 60 months. (Batch No. KTM06130016, KTM06130017 & KTM06130018)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, pharmaceutical

		development, manufacturer, description of manufacturing process and controls, specifications, analytical procedure, verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Toradol Ampoule 30mg, B. No. C2436, Mfg. date 01, 2020 by Barrett Hodgson by performing quality tests (Description, Identification, pH, Assay, Sterility, Bacterial endotoxin.)		
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.		
API Lot No.		KTM180021.		
Description of Pack (Container closure system)		Multi-colour unit carton having ALU/PVC tray containing 5 Glass ampoules filled with almost colorless to slight yellow sterile solution.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 24 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.		A-745	A-737	A-703
Batch Size		30,000 Ampoules	30,000 Ampoules	30,000 Ampoules
Manufacturing Date		10-2019	10-2019	10-2019
Date of Initiation		26-10-2019	26-10-2019	26-10-2019
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. Drugs (3) Pb. 2021/3124 dated 25-06-2021 for M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India issued by Food & Drugs Administration, Punjab is submitted by the firm. GMP certificate is valid till 25-06-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. SCL/2019-20/087 dated 25-07-2019 mentioning 15kg of ketorolac Tromethamine USP with B. No. KTM180021 attested by Assistant Director I&E, DRAP, Islamabad dated 02-08-2019.		

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response by the firm
1.	1.4.3	• Valid copy of GMP certificate of the contract acceptor shall be submitted. • Valid copy of GMP certificate/last inspection report and DML of the applicant shall be submitted as submitted DML is from 15-06-2011.	
2.	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	
3.	2.3	Table for literature references has mentioned USP for drug substance. Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	
4.	3.2.S.4.3	Analytical method validation studies performed by the drug substance manufacturer for assay test on HPLC has mentioned run time of 40 minutes. While the submitted chromatograms by the drug product manufacturer for method verification has run time of 12.5 minutes only. Justification shall be submitted.	
5.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Innovator has used Ethanol while the applied formulation has no ethanol. Applied formulation has used Citric acid anhydrous as preservative while the innovator has no citric acid. Justification shall be submitted.	
6.	3.2. P.2.3	Justification of not performing terminal sterilization of the drug product shall be submitted.	
7.	3.2.P.5.2	Analytical procedures submitted by the firm has mentioned 0.06mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. While USP has mentioned 0.05mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. Justification shall be submitted.	
8.	3.2.P.8	• Analytical procedures submitted by the finished product manufacturer as well as USP has mentioned injection volume of 100µl while the submitted chromatograms for the stability data reflects 20µl injection volume. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

523.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI, Industries Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☐Manufacturer. ☐ Importer. ☒ Is involved in none of the above (contract giver).

	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 3-8/2007-Lic dated 05-05-2010 wherein they changed their Tablet (Psychotropic) section to Tablet (General) section.
	Status of application	☒New Drug Product (NDP). ☐Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No 485 dated 05-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 9066774616 dated 01-12-2022.
	The proposed proprietary name / brand name	**Ticafold 90mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ticagrelor .....90mg.
	Pharmacotherapeutic Group of (API)	Farnesoid X Receptor Agonists. Platelet aggregation inhibitors excl. heparin.
	Pharmaceutical form of applied drug	Film coated tablets.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	2 x 10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Brilinta 90 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 90mg, PharmEvo (Pvt.) Ltd., Reg. No.089382.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Yangkou Chemical Industrial park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China. Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of the drug substance regarding nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. RD-TG-202101041, Mfg. date 04-01-2021) and

		justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (140901, 141001 & 141101)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description and composition, formulation development, manufacturer, description of manufacturing process and controls, batch formula, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against Anplag 90mg tablets, Batch No. 0N118, Mfg. date 12-2020 manufactured by PharmEvo by performing quality tests (Identification, Assay, Dissolution). CDP is performed in four BCS media across the physiological pH range i.e. 0.1 N HCl, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer and Tween 80 in water. The values are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China.		
API Lot No.	RD-TG-201911211.		
Description of Pack (Container closure system)	Alu-Alu blister of 2 x 10's further packed in a bleech card unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	21-04-2021	21-04-2021	21-04-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice number CY121078 dated 04-03-2021 mentioning 0.5kg quantity of ticagrelor, Batch No. RD-TG-202101041 attested by Assistant Director DRAP, Peshawar vide No. 812/12-03-2021 dated 12-03-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section	Observations.	Response by the firm.
1.	1.1	Form 5F shall be from the applicant instead of the contract acceptor with complete address of the applicant.	
2.	1.3.4	• Valid copies of DML of both the applicant as well as the contract acceptor shall be submitted. • Valid copies of GMP certificate/last inspection reports conducted within last three years of both the applicant as well as the contract acceptor shall be submitted.	
3.	1.5.5	Revise Pharmacotherapeutic Group to Platelet aggregation inhibitors excl. heparin as per WHO ATC code with submission of applicable fee.	
4.	1.5.6	This section has mentioned innovator specifications while the official monograph is available in BP. Clarification is required.	
5.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted.	
6.	2..3	Table for literature references has not mentioned any pharmacopoeia neither for the drug substance nor for the drug product while the official monograph for both the drug substance as well as drug product is available in BP. Justification shall be submitted.	
7.	3.2.S.2 & 3.2.S.3	Clear and readable copy of the information related to the drug substance shall be submitted. From section 3.2.S.2.2 to 3.2.S.3 as provided one is not in readable form.	
8.	3.2.S.4.1	• Specification of the drug substance by the finished product manufacturer shall be submitted. • Specifications provided by the drug substance manufacturer for the drug substance has assay limit of 98% - 102% while BP has mentioned 97.5% - 102%. Clarification shall be submitted.	
9.	3.2.S.4.2	Analytical procedures for the drug substance from both the drug substance manufacturer and finished product manufacturer shall be submitted.	
10.	3.2.S.4.4	The reference product literature specifies polymorphic form II for ticagrelor tablets whereas no such declaration has been made in the COA of drug substance.	
11.	3.2.S.4.5	Justification of specifications shall be submitted drug substance.	

	12.	3.2.S.5	CoA of primary / secondary reference standard including source and lot number shall be submitted.		
	13.	3.2.P.2.2	• Justification for not performing CDP against the innovator product. • Justification shall be submitted for not performing content uniformity test in the pharmaceutical equivalence studies. • In pharmaceutical equivalence dissolution studies of the finished trial batch shall be submitted instead of giving the results of CDP.		
	14.	3.2.P.5.1	• This section has mentioned in-house specifications while the official monograph of the applied formulation is available in BP. • Dissolution limits provided by the drug product manufacturer (NLT 75% after 75 minutes) are different from official monograph (Q = 70% after 45 minutes). Justification shall be submitted.		
	15.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.		
	16.		• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number shall be submitted. • Chromatograms submitted does not depicts any wavelength applied. Justification shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Reference of previous approval of applications with stability study data shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.		
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.					

Case No. 03; Registration applications of locally manufactured Human deferred cases on form 5F.

524.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Dry powder injectable (Carbapenem). – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7691 dated 17-03-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 5617000971 Dated 21-02-2023.
	The proposed proprietary name / brand name	**Morefen 500mg Dry Powder injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Meropenem as trihydrate 500mg
	Pharmacotherapeutic Group of (API)	Carbapenem.
	Pharmaceutical form of applied drug	Powder for injection.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's (one vial packed with 10ml of WFI).
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Merrem 500mg & 1gm injection by Pfizer Injectable, USFDA approved.
	For generic drugs (me-too status)	Meronem IV 500mg Injection, Pfizer Pakistan, Reg. No. 096203.
	Name and address of API manufacturer.	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (MRPS-0422032) and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. Batch No. MRPS-0218002, MRPS-0218003 & MRPS-0218004.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Meroget 500mg injection, batch No. 9210407003, mfg. date 04-2021manufactured by Getz pharma by performing quality test pH, Loss on Drying, Assay of Meropenem, assay of sodium content and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.		
API Lot No.	MRPS-0422032.		
Description of Pack (Container closure system)	White to off white crystalline powder filled in a glass vial and properly sealed.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 Vials	300 Vials	300 Vials
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	04-08-2022	04-08-2022	04-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. DC/A-I/2020/1517 dated 09-09-2020 issued by Drug Control Organization, Rajasthan, Jaipur. Valid till 11-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not readable.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		First page of Form 5F is not provided.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. DC/A-4/GMP/2022/2804 dated 07-09-2022 issued by Food Safety and Drugs Control Commissionerate (Drugs Control Wing) Rajasthan, India valid till 08-09-2023.
3.	2.3	• Revised table for literature references with correct information regarding the drug substance and finished product with applicable fee shall be submitted. • Justify the actual quantity/vial against mentioned in executed BMR's the potency of drug substance.	Firm has provided corrected information with submission of 7500/- fee vide slip No. 01832409787 dated 10-07-2023. Firm has submitted that actual weight per vial was calculated after adjustment of assay and factor. Factor = 1.140 Potency = 83.56% 500 x 1.140/83.56 x 100 = 682.14
4.	3.2.S.4.1	Specification of the drug substance submitted by the drug substance manufacturer are for Ampicillin sodium instead of Meropenem. Justification shall be submitted.	Firm has submitted that during compilation of dossier, specifications for ampicillin were attached instead of Meropenem. They also submitted new specification for Meropenem.
5.	3.2.S.4.5	Justification of specification for the drug substance is for Doxycycline USP. Justify?	Firm has submitted that it was typo error and they also attached justification of specifications for Meropenem.
6.	3.2.S.7	• Clear and readable copies of the stability data sheets for drug substance shall be submitted. • Stability study data for the drug substance submitted is for Meropenem USP only. Justification shall be submitted. • Stability data sheets for the drug substance has also not mentioned sodium content. Justify. • Real time stability data is only for 09 months. Complete real time stability data shall be submitted.	Submitted. Firm has submitted that stability for drug substance is Meropenem trihydrate blended with sodium carbonate as evident from the specifications. Drug substance manufacturer writes product name as per USP monograph i.e. Meropenem USP Sterile. Real time stability study data for 48 months is submitted by the firm.
7.	3.2.P.1	Justify the proposed quantity/vial against the potency limit of drug substance declared in 3.2.S.4.1.	Firm has submitted that actual weight per vial was calculated after adjustment of assay and factor. Factor = 1.140 Potency = 83.56% 500 x 1.140/83.56 x 100 = 682.14
8.	3.2.P.2.2	• Justification shall be submitted for not performing pharmaceutical equivalence against the innovator product.	Firm has submitted that they have also performed pharmaceutical equillance studies against the Meronem injection ofM/s Pfizer Pakistan limited.

			• Content uniformity test and particulate matter tests are not performed in the pharmaceutical equivalence studies. Justify?	They also provided the new pharmaceutical equivalence studies of their product against the Meronem 500mg injection with batch No. 5B22H31, mfg. date 04-2022 by performing quality tests including pH, water content, uniformity of dosage unit, particulate matter, Assay of Meropenem, assay of sodium content and sterility.
	9.	3.2.P.8	• Evidence of availability of atomic absorption spectroscopy shall be submitted. • Clear and readable copy of the clearance certificate for import of API shall be submitted. • Raw data sheets for calculation of assay of Meropenem and sodium content at each time interval with calculation formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted that they have attached commercial invoice for atomic absorption. However, no such invoice is attached. Firm has submitted copy of clearance certificate No. E-1393520227361 dated 07-06-2022 mentioning 0.50 grams of Meropenem with batch number of MRPS-0422032, mfg. date 30-Apr-2022. Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Submitted. Submitted.

Decision of 330th meeting of Registration Board: Deferred for following;

- Evidence of availability of atomic absorption spectroscopy shall be submitted.
- Raw data sheets for calculation of assay of Meropenem and sodium content at each time interval with calculation formula shall be submitted.
- Justification shall be submitted regarding the quantity of drug substance imported i.e 0.5grams vide clearance certificate No. E-1393520227361 dated 07-06-2022 against the manufactured six trial batches of two different strengths of 500mg and 1gm with each trial of 300 vials.

Reply submitted by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Evidence of availability of atomic absorption spectroscopy shall be submitted.	Firm has submitted copy of invoice No. 11/772 dated 03-11-2021 for purchase of Atomic Absorption thermos model ICE-3300.
2.	Raw data sheets for calculation of assay of Meropenem and sodium content at each time interval with calculation formula shall be submitted.	Firm has submitted raw data sheets for calculations of assay and sodium content.
3.	Justification shall be submitted regarding the quantity of drug substance imported i.e 0.5grams vide clearance certificate No. E-1393520227361 dated 07-06-2022 against	Firm has submitted a loan letter from M/s Stallion pharma wherein they have taken following API on loan for development purpose;

		the manufactured six trial batches of two different strengths of 500mg and 1gm with each trial of 300 vials.	Meropenem Trihydrate, Imipenem and Cilastatin and Potassium Clavulanate with Syloid (1:1) Firm has also submitted copy of clearance certificate No. E-686642824781 mentioning 100kg of Meropenem Sodium Carbonate Sterile (USP Specification) with batch No. UIMRPS21065, mfg.date 01-Feb-2022.	

Decision: Approved.

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

525.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Dry powder injectable (Carbapenem). – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7692 dated 17-03-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 5843354846 Dated 21-02-2023.
	The proposed proprietary name / brand name	**Morefen 1gm Dry Powder injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Meropenem as trihydrate 1gm
	Pharmacotherapeutic Group of (API)	Carbapenem.
	Pharmaceutical form of applied drug	Powder for injection.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's (one vial packed with 10ml of WFI).
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Merrem 500mg & 1gm injection by Pfizer Injectable, USFDA approved.

	For generic drugs (me-too status)	Meronem IV 1gm Injection, Pfizer Pakistan, Reg. No. 096204.
	Name and address of API manufacturer.	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (MRPS-0422032) and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. Batch No. MRPS-0521005, MRPS-0521006 & MRPS-0521005.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Meroget 1gm injection, batch No. 9210407004, mfg. date 04-2021 manufactured by Getz pharma by performing quality test pH, Loss on Drying, Assay of Meropenem, assay of sodium content and sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.
API Lot No.	MRPS-0422032.
Description of Pack	White to off white crystalline powder filled in a glass vial and properly sealed.

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 Vials	300 Vials	300 Vials
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	04-08-2022	04-08-2022	04-08-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. DC/A-I/2020/1517 dated 09-09-2020 issued by Drug Control Organization, Rajasthan, Jaipur. Valid till 11-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not readable.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		First page of Form 5F is not provided.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. DC/A-4/GMP/2022/2804 dated 07-09-2022 issued by Food Safety and Drugs Control Commissionerate (Drugs Control Wing) Rajasthan, India valid till 08-09-2023.
3.	2.3	• Revised table for literature references with correct information regarding the drug substance and finished product with applicable fee shall be submitted. • Justify the actual quantity/vial against mentioned in executed	Firm has provided corrected information with submission of 7500/- fee vide slip No. 01832409787 dated 10-07-2023. Firm has submitted that actual weight per vial was calculated after adjustment of assay and factor.

			BMR's the potency of drug substance.	Factor = 1.140 Potency = 83.56% 1000 x 1.140/83.56 x 100 = 1364.29	
	4.	3.2.S.4.1	Specification of the drug substance submitted by the drug substance manufacturer are for Ampicillin sodium instead of Meropenem. Justification shall be submitted.	Firm has submitted that during compilation of dossier, specifications for ampicillin were attached instead of Meropenem. They also submitted new specification for Meropenem.	
	5.	3.2.S.4.5	Justification of specification for the drug substance is for Doxycycline USP. Justify?	Firm has submitted that it was typo error and they also attached justification of specifications for Meropenem.	
	6.	3.2.S.7	• Clear and readable copies of the stability data sheets for drug substance shall be submitted. • Stability study data for the drug substance submitted is for Meropenem USP only. Justification shall be submitted. • Stability data sheets for the drug substance has also not mentioned sodium content. Justify. • Real time stability data is only for 09 months. Complete real time stability data shall be submitted.	Submitted. Firm has submitted that stability for drug substance is Meropenem trihydrate blended with sodium carbonate as evident from the specifications. Drug substance manufacturer writes product name as per USP monograph i.e. Meropenem USP Sterile. Real time stability study data for 48 months is submitted by the firm.	
	7.	3.2.P.1	Justify the proposed quantity/vial against the potency limit of drug substance declared in 3.2.S.4.1.	Firm has submitted that actual weight per vial was calculated after adjustment of assay and factor. Factor = 1.140 Potency = 83.56% 1000 x 1.140/83.56 x 100 = 1364.29	
	8.	3.2.P.2.2	• Justification shall be submitted for not performing pharmaceutical equivalence against the innovator product. • Content uniformity test and particulate matter tests are not performed in the pharmaceutical equivalence studies. Justify?	Firm has submitted that they have also performed pharmaceutical equillance studies against the Meronem injection of M/s Pfizer Pakistan limited. They also provided the new pharmaceutical equivalence studies of their product against the Meronem 500mg injection with batch No. 5B22H31, mfg. date 04-2022 by performing quality tests including pH, water content, uniformity of dosage unit, particulate matter, Assay of Meropenem, assay of sodium content and sterility.	
	9.	3.2.P.8	• Evidence of availability of atomic absorption spectroscopy shall be submitted. • Clear and readable copy of the clearance certificate for import of API shall be submitted.	Firm has submitted that they have attached commercial invoice for atomic absorption. However, no such invoice is attached. Firm has submitted copy of clearance certificate No. E-1393520227361 dated 07-06-2022 mentioning 0.50 grams of Meropenem with batch	

			• Raw data sheets for calculation of assay of Meropenem and sodium content at each time interval with calculation formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	number of MRPS-0422032, mfg. date 30-Apr-2022. However, the actual quantity used in three trial batches is much more than the imported. Not submitted. Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Submitted. Submitted.	

Decision of 330th meeting of Registration Board: Deferred for following;

- Evidence of availability of atomic absorption spectroscopy shall be submitted.
- Raw data sheets for calculation of assay of Meropenem and sodium content at each time interval with calculation formula shall be submitted.
- Justification shall be submitted regarding the quantity of drug substance imported i.e 0.5grams vide clearance certificate No. E-1393520227361 dated 07-06-2022 against the manufactured six trial batches of two different strengths of 500mg and 1gm with each trial of 300 vials.

Reply submitted by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Evidence of availability of atomic absorption spectroscopy shall be submitted.	Firm has submitted copy of invoice No. 11/772 dated 03-11-2021 for purchase of Atomic Absorption thermos model ICE-3300.
2.	Raw data sheets for calculation of assay of Meropenem and sodium content at each time interval with calculation formula shall be submitted.	Firm has submitted raw data sheets for calculations of assay and sodium content.
3.	Justification shall be submitted regarding the quantity of drug substance imported i.e 0.5grams vide clearance certificate No. E-1393520227361 dated 07-06-2022 against the manufactured six trial batches of two different strengths of 500mg and 1gm with each trial of 300 vials.	Firm has submitted a loan letter from M/s Stallion pharma wherein they have taken following API on loan for development purpose; Meropenem Trihydrate, Imipenem and Cilastatin and Potassium Clavulanate with Syloid (1:1) Firm has also submitted copy of clearance certificate No. E-686642824781 mentioning 100kg of Meropenem Sodium Carbonate Sterile (USP Specification) with batch No. UIMRPS21065, mfg. date 01-Feb-2022.

Decision: Approved.

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

526.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**

	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.
	Evidence of approval of manufacturing facility	Capsule (Penicillin) – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 5263 dated 23-02-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 915463761131 Dated 06-01-2023.
	The proposed proprietary name / brand name	**Ampiwell 250mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Ampicillin as trihydrate 250mg
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	20 capsules.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ampicillin Capsules BP 250 mg, Crescent Pharma Limited, MHRA approved.
	For generic drugs (me-too status)	Penbritin 250mg Capsule, GSK Pakistan, Reg. No. 000188.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore. Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and

		controls, specifications, analytical procedures and its verification, batch analysis (B. No. 00003/093/2021, mfg. date 11-2021) and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data sheets for the drug substance. However, the stability data sheets are not in readable form. B. No. 00003/001/2018, 00003/002/2018 & 00003/003/2018,
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution of their applied formulation with Penbritin 250mg capsule with B. No. IPBAB in three different mediums of pH 1.2, 4.5 & 6.8. values of the F2 are in acceptable range. Firm has submitted pharmaceutical equivalence of their product against the Penbritin 250mg capsule by performing quality tests od identification, average filled weight, dissolution and assay.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.		
API Lot No.	00003/093/2021.		
Description of Pack (Container closure system)	Almost white granular powder filled in purple and white capsule packed in printed Alu - Alu blister of 20 capsules further packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A	B	C
Batch Size	800 Capsules	800 Capsules	800 Capsules
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Proforma invoice No. PL/P-INV/HO/866 dated 03-01-2022 wherein they have purchased 1kg of Ampicillin trihydrate from M/s Pharmagen Limited. However, the invoice has not mentioned any batch number and manufacturing date of the drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02-09-2020 issued on the basis of inspection conducted on 22-06-2020. GMP certificate is not within last three years.
2.	2.3	Table for literature references with correct information with applicable fee shall be submitted.	Firm has provided corrected information with submission of 7500/- fee vide slip No. 7428934818 dated 10-07-2023.
3.	3.2.S.7	Readable copies of the drug substance stability data sheets shall be submitted.	Not submitted.
4.	3.2.P.2.2	• Dissolution time is not mentioned in the pharmaceutical equivalence. Justification shall be submitted. • CDP sheets have mentioned Ampicillin sodium as drug substance. Justification shall be submitted.	Firm has submitted that dissolution time is mentioned in specifications and CDP. Firm has submitted that it was typo error and they attached updated CDP sheets. *However, in the updated CDP sheets no dissolution medium is mentioned. Furthermore, the values at different time points are completely different from that of the originally submitted.*
5.	3.2.P.5.1	Justification shall be submitted for adopting all the specifications for the finished product from BP while only dissolution test is adopted from USP.	Firm has submitted that in BP monograph of ampicillin capsule, dissolution test has not been given, so they adopted dissolution test from USP.
6.	3.2.P.8	• Proforma invoice provided by the firm has not mentioned any batch number and mfg. date. Clarify. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm has submitted new invoice wherein they have added batch number of the material used in trial batches. *However, the batch number mentioned in COAs and stability data sheet is (B. No. 00003/093/2021) while the new submitted*

			invoice has mentioned B. No. 00003-11/093/2021.	

Decision of 330th meeting of Registration Board: Deferred for following;

- Valid copy of GMP certificate/inspection report conducted within last three years of the drug substance manufacturer shall be submitted.
- Readable copies of the drug substance stability data sheets shall be submitted.
- Firm will perform Comparative Dissolution of their applied product with innovator product with complete details of the mediums, time points and details of the innovator product.
- Clarification regarding the API lot number as it is different in COAs, stability data sheets and submitted invoice.

Reply submitted by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Valid copy of GMP certificate/inspection report conducted within last three years of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 204/2022-DRAP (AD/159531263130-530) dated 22-11-2022 issued on the basis of inspection conducted on 18-11-2022.
2.	Readable copies of the drug substance stability data sheets shall be submitted.	Firm has submitted stability data sheets for the drug substance in readable form. B. No. 00003/001/2015, 00003/002/2015 & 00003/003/2015.
3.	Firm will perform Comparative Dissolution of their applied product with innovator product with complete details of the mediums, time points and details of the innovator product.	Firm has submitted CDP results of their applied formulation against the brand i.e. Penbritin 250mg capsules, Batch No. B. WV7H manufactured by M/s GSK Pakistan in three mediums of pH 1.2, pH 4.5 & pH 6.8. values of F_2 are in acceptable ranges.
4.	Clarification regarding the API lot number as it is different in COAs, stability data sheets and submitted invoice.	Firm has submitted a document from M/s Pharmagen pharma wherein they certified that they have supplied material with Ampicillin trihydrate, B. No. 00003-11/093/2021 to M/s Fynk Pharma. They also they also submitted copy of invoice No. 1583 mentioning the same material with batch number.

Decision: Approved.

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

527.	Name, address of Applicant / Marketing Authorization Holder	**M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 45/2021-DRAP (K) dated 29-09-2021 on the basis of inspection conducted on 27-09-2021 is submitted.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale

		☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8513, dated 01/04/2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 94389054 dated: 03/02/2022.
	The proposed proprietary name / brand name	Sulfadene Cream 1% w/w.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Silver sulfadiazine..... 10mg
	Pharmacotherapeutic Group of (API)	Sulfonamides. (D06BA)
	Pharmaceutical form of applied drug	Topical cream.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	15gm.
	Proposed unit price	Rs. 150/15gm Aluminum tube.
	The status in reference regulatory authorities	Silvadene 1% (Silver Sulfadiazine) cream, USFDA approved.
	For generic drugs (me-too status)	Quench 1% cream, Ferozsons laboratory, Reg. No. 013090.
	Name and address of API manufacturer.	Srikem Laboratories (Pvt.) Limited, Taloja, Navi Mumbai Plot No. 17/24, 17/22, 17/23, 17/13 M.I.D.C Taloj-410 208, Taluka Panvel. Dist. Raigad (Maharashtra) India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (214001015, Mfg. date 08-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 194001001, 194001002 & 194001003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceuticaldevelopment, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch

		analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence studies of their product against Dermazin by performing identification, pH, fill volume and drug release. However, drug release has mentioned limit of 75% - 133% and no details of the comparator product are submitted.
	Analytical method validation/verification of product	Not submitted.

STABILITY STUDY DATA

Manufacturer of API	Srikem Laboratories (Pvt.) Limited, Taloja, Navi Mumbai Plot No. 17/24, 17/22, 17/23, 17/13 M.I.D.C Taloj-410 208, Taluka Panvel. Dist. Raigad (Maharashtra) India..		
API Lot No.	Not mentioned.		
Description of Pack (Container closure system)	Sulfadene cream 1% w/w will be supplied in Aluminum tube packed in unit carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months. Accelerated: 06 months.		
Frequency	Real Time: 0,3,6, 9, 12, 18 & 24 (Months) Accelerated: 0, 03 & 06 (Months).		
Batch No.	TB 101	TB 102	TB 103
Batch Size			
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm

	1.	1.3.4	Valid copy of DML of the applicant shall be submitted.		
	2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.		
	3.	1.6.5	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.		
	4.	2.3	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.		
	5.	3.2.S.2 & 3.2.S.3	Detailed information of these sections shall be submitted.		
	6.	3.2.S.4.1	• Specifications of the drug substance by the drug substance manufacturer shall be submitted. • USP monograph has mentioned limits for Nitrate while the specifications provided by the drug product manufacturer has no limits for nitrate. Clarification shall be submitted.		
	7.	3.2.S.4.2	Analytical procedures for the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.		
	8.	3.2.S.4.3	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted. • Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.		
	9.	3.2.S.4.4	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug product manufacturer as it has mentioned test date of 12-1-2018.		
	10.	3.2.P.2.2	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.		
	11.	3.2.P.5.2	• Wavelength is not mentioned in the chromatographic condition of the assay test in analytical procedure. • Calculation formula used for assay test in the analytical procedures shall be submitted.		
	12.	3.2.P.5.3	Analytical method verification studies of the finished product along with analytical record shall be submitted.		
	13.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the final concentration of both standard and sample preparation are completely different. • Justification shall be submitted regarding the submitted chromatograms as no information is available on them neither any wavelength is mentioned on them. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.		

			• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.		

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Reason for deferment.	Reply by the firm
1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000488 with renewal date from 05-05-2021.
2.	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	Firm has submitted copy of letter No. F. 2-4/98-Lic(Pt-I) dated 07-06-2022 mentioning Sterile eye ointment/Topical cream (General).
3.	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.	Submitted.
4.	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.	Firm has submitted revised table for literature references. ***However, information is not corrected in the table. Furthermore, no fee is submitted by the firm.*** Submitted.
5.	Detailed information of these sections shall be submitted.	Submitted.
6.	• Specifications of the drug substance by the drug substance manufacturer shall be submitted. • USP monograph has mentioned limits for Nitrate while the specifications provided by the drug product manufacturer has no limits for nitrate. Clarification shall be submitted.	Submitted. Firm has submitted that drug substance manufacturer has revised specifications as per USP. Therefore, it is requested to go through the CTD application process, may kindly be approval in our favor at the earliest convenience. ***No clarification is submitted by the firm regarding nitrate limits.***
7.	Analytical procedures for the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	Firm has submitted analytical procedures from both the drug substance manufacturer and drug product manufacturer. ***However, the analytical procedures from drug product manufacturer is different from both the USP monograph and drug substance manufacturer as the assay method used by the USP monograph and drug substance manufacturer is by HPLC while the assay method provided by the drug product manufacturer is by titration.***
8.	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted updated analytical method verification studies for the drug product. ***Analytical method verification studies for drug substance not provided.*** ***No clarification is submitted by the firm against this point.***

	• Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.		
9.	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug product manufacturer as it has mentioned test date of 12-1-2018.	Firm has submitted COA of the drug substance with batch number 214001015, mfg. date August 2018 and retest date of July 2023. ***Not submitted.*** Firm has submitted that date on the COA of the drug substance had been printed wrong.	
10.	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.	Firm has submitted new studies of pharmaceutical equivalence against Quench cream, batch No. 15-08-2018 manufactured by Ferozsons Laboratories Limited by performing quality tests of identification, pH, weight fill comparison and drug release.	
11.	• Wavelength is not mentioned in the chromatographic condition of the assay test in analytical procedure. • Calculation formula used for assay test in the analytical procedures shall be submitted.	Firm has submitted new analytical procedures in line with USP monograph.	
12.	Analytical method verification studies of the finished product along with analytical record shall be submitted.	Submitted.	
13.	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the final concentration of both standard and sample preparation are completely different. • Justification shall be submitted regardingthe submitted chromatograms as no information is available on them neither anywavelength is mentioned on them. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted new stability data sheetswherein they have mentioned 1kg of batch size and 214001015 as API lot number. Firm has submitted that preparation of standard and sample solution has been revised to an easy format for clear and easy understanding. ***However, no justification is submitted. In the initially submitted data both the standard solution and sample solution were completely different from each other.*** Firm has submitted that in old version of HPLC software system this information was not added in chromatograms. As per regulatory requirements, the software has been updated. The stability data after upgradation is reprinted for regulatory convenience. Firm has submitted that stability of the product had been conducted at 65% ± 5% RH. By mistake the results of the stability were compiled on the stability sheets of eye drops. ***Not submitted.*** Firm has submitted copy of GMP certificate No. 6107596 dated 01-07-2022 issued by Food & Drug Administration Maharashtra State India valid till 30-06-2023.	

		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	***GMP certificate is not valid.*** ***Not submitted.*** ***Not submitted.*** Submitted.	

Decision: Deferred for following:

- **Firm will submit full fee of 30,000/- for pre-approval changes/corrections in registration application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted.**
- **Justification shall be submitted regarding the analytical procedures as the assay method used by the USP monograph and drug substance manufacturer is by HPLC while the assay method provided by the drug product manufacturer is by titration.**
- **Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted.**
- **Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.**
- **Analytical record of the drug substance shall be submitted.**
- **Approval of API/ DML/GMP certificate (Valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.**
- **Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.**
- **Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.**

528.	Name, address of Applicant / Marketing Authorization Holder	**M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 45/2021-DRAP (K) dated 29-09-2021 on the basis of inspection conducted on 27-09-2021 is submitted.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9835, dated 18/04/2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 13582877112 dated: 03/02/2022.
	The proposed proprietary name / brand name	Cerucil Sterile Ear Drops.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ciprofloxacin as HCl..... 3mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic.
	Pharmaceutical form of applied drug	Otic drops.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	10ml.
	Proposed unit price	Ear drops 10ml RS; 118.66.
	The status in reference regulatory authorities	Could not be confirmed.
	For generic drugs (me-too status)	Cipotic Ear Drops, Barrett Hodgson, Reg. No. 032485.
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co., Ltd., No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and technological development area, Shangyu, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (DK15-2111042a, Mfg. date 11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 0701192, 0701193 & 0701194.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control ofdrug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence studies of their product against Cipotec by performing identification, pH, fill volume and drug release. However, drug release has mentioned limit of 75% - 133% and no details of the comparator product are submitted.
	Analytical method validation/verification of product	Not submitted.
STABILITY STUDY DATA		

Manufacturer of API	Shangyu Jingxin Pharmaceutical Co., Ltd., No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and technological development area, Shangyu, Zhejiang Province, China.		
API Lot No.	Not mentioned.		
Description of Pack (Container closure system)	Plastic bottle with cap and nozzle packed in carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months. Accelerated: 06 months.		
Frequency	Real Time: 0,3,6, 9, 12, 18 & 24 (Months) Accelerated: 0, 03 & 06 (Months).		
Batch No.	TB-101	TB-102	TB-103
Batch Size			
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	
3.	1.5.4	In some sections 5ml pack size is mentioned while in some 10 ml is mentioned. Clarification and exact pack size shall be mentioned.	
4.	1.5.6	This section has mentioned USP specifications. However, official monograph for ciprofloxacin HCl is not available in USP. Clarification shall be submitted.	
5.	1.5.9	Evidence of approval of applied formulation in reference regulatory authorities as approved by Registration Board in its 275th meeting shall be submitted.	

	6.	1.6.5	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.		
	7.	2.3	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.		
	8.	3.2.S.2 & 3.2.S.3	Detailed information of these sections shall be submitted.		
	9.	3.2.S.4.1	Specifications of the drug substance from both drug substance and drug product manufacturer shall be submitted.		
	10.	3.2.S.4.2	Analytical procedures of the drug substance from both drug substance and drug product manufacturer shall be submitted.		
	11.	3.2.S.4.3	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted. • Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.		
	12.	3.2.S.4.4	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug substance manufacturer as it has mentioned mfg. date of 04-11-2021 while trial batches are manufactured in May, 2019.		
	13.	3.2.S.5	Details and COA of the working standard used shall be submitted.		
	14.	3.2.S.7	Justification shall be submitted for not including most of the test in the stability of the drug substance.		
	15.	3.2.P.2.2	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.		
	16.	3.2.P.5.1	• Reference to the finished product specification shall be submitted. • Specifications has mentioned Assay limit of 90-110% while BP monograph for Ciprofloxacin Ear drops has mentioned 95-110%. Clarification shall be submitted. • Specifications has mentioned pH limit of 3.5 to 5.5 while BP monograph for Ciprofloxacin Ear drops has mentioned 4 to 5. Clarification shall be submitted		
	17.	3.2.P.5.2	Justification shall be submitted for the analytical procedures as they are completely different from the official monograph of BP.		
	18.	3.2.P.5.3	Analytical method verification studies of the finished product along with analytical record shall be submitted.		
	19.	3.2.P.5.6	Justification of specifications has mentioned Manufacturer specifications while section 1.5.6 has mentioned USP specification. Official monograph for ciprofloxacin Ear drops is available in BP. Justification shall be submitted.		
	20.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the final concentration of both standard and sample preparation are completely different. • Justification shall be submitted for using UV method for the analysis of the assay test in stability studies. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted.		

			• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.		

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Reason for deferment.	Reply by the firm
1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000488 with renewal date from 05-05-2021.
2.	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	Firm has submitted copy of letter No. F. 2-4/98-Lic(Pt-I) dated 07-06-2022 mentioning Eye/ear drops.
3.	In some sections 5ml pack size is mentioned while in some 10 ml is mentioned. Clarification and exact pack size shall be mentioned.	Firm has submitted that by typing mistake 10ml is printed instead of 5ml. the actual pack size of 5ml is corrected.
4.	This section has mentioned USP specifications. However, official monograph for ciprofloxacin HCl is not available in USP. Clarification shall be submitted.	***No clarification is submitted by the firm. However, they submitted Ciprofloxacin Ear drops monograph from BP.*** ***Firm has also submitted new information wherein they have changed their specifications from USP to BP without submission of any fee.***
5.	Evidence of approval of applied formulation in reference regulatory authorities as approved by Registration Board in its 275th meeting shall be submitted.	Firm has submitted Ciloquin 3mg/ml ear drops as evidence of RRA. Ciloquin 3mg/ml ear drops approved by TGA Australia.
6.	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.	Firm has submitted copy of GMP certificate No. SY 31052018 dated 25-05-2016 issued by CFDA valid till 05-24-2021. ***Validity is expired.***
7.	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.	***Firm has submitted table for literature references with incorrect information of the drug product.*** ***Not submitted.***
8.	Detailed information of these sections shall be submitted.	Submitted.
9.	Specifications of the drug substance from both drug substance and drug product manufacturer shall be submitted.	Submitted.
10.	Analytical procedures of the drug substance from both drug substance and drug product manufacturer shall be submitted.	Submitted.
11.	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted. • Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug	Submitted.

		product manufacturer as that of the drug substance manufacturer.	
	12.	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug substance manufacturer as it has mentioned mfg. date of 04-11-2021 while trial batches are manufactured in May, 2019.	Firm has submitted COA of the drug substance however, no details are submitted regarding batch number, Mfg. date and Exp. date etc. ***Submitted. However, in the submitted analytical record concentration of the test solution and concentration of the reference solution are completely different from each other's.*** Firm has submitted that ciprofloxacin HCl is used in the manufacturing of product "Ophth Cipro" by the drug product manufacturer. During compilation of the dossier file mistakenly the assistant had enclosed copy of new consignment of the material instead of the old one.
	13.	Details and COA of the working standard used shall be submitted.	*Submitted.*
	14.	Justification shall be submitted for not including most of the test in the stability of the drug substance.	Firm has submitted new stability data sheets for the drug substance from drug substance manufacturer.
	15.	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.	Firm has submitted pharmaceutical equivalence studies of their applied formulation against the Ciloquin 3mg/ml ear drops, batch No. FDT258, manufacturing date of 02-2019 manufactured by M/s Novartis pharma Australia by performing identification, fill volume, pH, assay and sterility. ***However, no pictorial evidence is submitted by the firm for innovator product.*** ***Firm has also submitted purchase invoice for the Ciloquin Ear drops from Time Medico Karachi.*** ***However, in the available data of registered products, there is no registration for the same product.***
	16.	• Reference to the finished product specification shall be submitted. • • Specifications has mentioned Assay limit of 90-110% while BP monograph for Ciprofloxacin Ear drops has mentioned 95-110%. Clarification shall be submitted. • Specifications has mentioned pH limit of 3.5 to 5.5 while BP monograph for Ciprofloxacin Ear drops has mentioned 4 to 5. Clarification shall be submitted	Firm has submitted that specifications of the product have been updated according to BP monograph. ***No justification is submitted by the firm.*** Firm has submitted that pH limit of the product has been updated as per BP monograph in the dossier that is 4 – 5.
	17.	Justification shall be submitted for theanalytical procedures as they are completelydifferent from the official monograph of BP.	Firm has submitted that specifications of the product have been updated according to BP monograph. ***However, in the initially submitted dossier all the submitted data was as per previous specifications and analytical procedures.***
	18.	Analytical method verification studies of the finished product along with analytical record shall be submitted.	Submitted.
	19.	Justification of specifications has mentioned Manufacturer specifications while section 1.5.6 has mentioned USP specification. Official	Firm has submitted that specifications of the product have been updated according to BP monograph.

	monograph for ciprofloxacin Ear drops is available in BP. Justification shall be submitted.		
20.	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the final concentration of both standard and sample preparation are completely different. • Justification shall be submitted for using UV method for the analysis of the assay test in stability studies. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted new stability data sheets with batch size of 1 liter and API lot No. DK0701192. ***However, the batch analysis provided in 3.2.S.4.4 has batch No. DK15-2111042a, Mfg. date 11-2021 and is changed from the submitted one.*** Firm has submitted that concentration of standard and sample solution has been updated. Standard and sample final concentration in the old testing method was same but it was different from the recent monograph. Firm has submitted that they have performed stability assay test on both techniques UV and HPLC. By mistake the record of HPLC testing could not be attached. We are sending you data on HPLC. Firm has submitted that as per stability guidelines of ICH Q1 A (R2), if a product is packed in a semipermeable container, the stability condition should be 35% ± 5% RH. ***Not submitted.*** Firm has submitted copy of GMP certificate No. SY 31052018 dated 25-05-2016 issued by CFDA valid till 05-24-2021. ***Validity is expired.*** ***Not submitted.*** ***Not submitted.*** Submitted.	

Decision: Deferred for following:

- **Firm will submit full fee of 30,000/- for pre-approval changes/corrections in registration application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted.**
- **Copies of executed BMR's shall be submitted.**
- **Justification shall be submitted regarding the newly submitted analytical record for the drug substance wherein the concentration of the test solution and concentration of the reference solution are completely different from each other's.**
- **Pictorial evidence of the innovator product with visible details of batch number, manufacturing date, expiry date etc. shall be submitted.**
- **Justification shall be submitted regarding registration status of the reference product against which Pharmaceutical equivalence studies have bene performed.**
- **Justification shall be submitted regarding the previously submitted analytical record wherein the analytical procedures were completely different from the official monograph of BP.**
- **Justification shall be submitted regarding the API lot number in the stability data sheet as it is changed from the *batch analysis provided in 3.2.S.4.4. i.e. DK15-2111042a, Mfg. date 11-2021.***

• **Approval of API/ DML/GMP certificate (Valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.** • **Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.** • **Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.**
Decision:

Case No. 04; Registration applications of locally manufactured Human deferred cases on form 5.

529.	Name and address of manufacturer/ Applicant	M/s Demont Research Laboratories, 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan.
	Brand Name + Dosage Form + Strength	Aspril 75/75mg Tablet.
	Composition	Each film- coated tablet contains: Clopidogrel as hydrogen sulphate (core enteric coated) ……..…75mg Aspirin (outer immediate core)..... 75mg
	Diary No. Date of R & I & fee	Dy.No.41393 dated 07-12-2018; Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- thrombotic.
	Type of Form.	Form- 5.
	Finished product Specification.	Manufacturers.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved.
	Me-too status.	Clopido Plus 75 Tablet of M/s Platinum Pharma, Karachi 055740
	GMP status.	Last GMP inspection was conducted on 26-02-2018 satisfactory and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator.	In EMA, the product has been developed as film-coated bilayer tablets containing two active substances while the firm has applied only film- coated tablets.
	Decision of 297th meeting of Registration Board.	Deferred for correction of formulation along with fee and evidence requisite bilayer machine.
	Submission by the firm:	Firm has submitted that they have dual core compression machine (ZP-33) and already have a registered bilayer product Mastador 75mg/200mcg tablets, Reg. No. 109304 which was registered after online stability data verification where the same machine was also the part of inspection. Firm has also provided registration letter of Mastador 75mg/200mcg tablets.
	Remarks of the Evaluator PEC-XIII	• Firm neither changed their label claim nor submitted any fee for change of label claim. • Latest GMP could not be confirmed.
	Decision of 316th meeting of Registration Board.	Deferred for revision of formulation to bi-layer tablet as per the innovator product along with submission of full fee.
	Submission by the firm:	Firm has submitted revised label claim for the applied formulation with submission of 30,000/- fee vide slip No. 93390802015 dated 01-11-2023. Firm has also submitted copy of GMP certificate No. 134/2023-DRAP (AD-265535911-876) dated 07-08-2023 on the basis of inspection conducted on 23-05-2023.

		Revised label claim is as under; **Each film- coated bilayer tablet contains:** **Clopidogrel as hydrogen Sulphate (core enteric coated) ……..…75mg** **Aspirin (outer immediate core).....75mg**
	Remarks of the Evaluator PEC-XIII	•
	Decision: Approved with following label claim; **Each film- coated bilayer tablet contains:** **Clopidogrel as hydrogen Sulphate (core enteric coated) ..... 75mg** **Aspirin (outer immediate core)..... 75mg** **Registration letter will be issued after submission of evidence of bilayer tablet machine.**	

Agenda of Evaluator PEC-XXI

Agenda Item No. 01:

Priority Applications of Human Drugs Locally Manufactured (New DML) applied on Form - 5F.

530.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22156 dated 08 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 31-08-2023 (Challan / Receipt # 37041984691)
	The proposed proprietary name / brand name	**GABEK 25mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin … 25mg (BP Specifications)
	Pharmacotherapeutic Group of (API)	N02BF02, Gabapentinoids / antiepileptic agents.

	Pharmaceutical form of applied drug	White to off-white powder filled in Hard Gelatin Capsule Shell.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA 25mg Capsules of UPJOHN (USFDA Approved).
	For generic drugs (me-too status)	GABICA 25mg Capsules by M/s. Getz Pharma (Pvt.) Ltd.
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd. Platinum Techno Park haware, Bhagwan Mahaveer Road, Sector 30, Vashi, Navi Mumbai, Maharashtra 400703, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GABICA 25mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GABICA 25mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., India.		
API Lot No.	PPR/21010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	03-02-2023	03-02-2023	03-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of commercial invoice attested by AD I&E DRAP, Islamabad has been submitted for Pregabalin USP Batch No. PPR/21010 for M/s Panacea Pharma, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	Response of the Firm
i. The submitted Real Time Stability Study Data of Drug Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH	Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation Studies in the

	for 24 Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*** No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	Finished Pharmaceutical Product upon completion of 01 Year.	
	ii. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The submitted GMP Certificate was valid till 02-11-2023.**	
	iii. Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.	
	iv. 2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.**	
	v. The dissolution specifications of FPP have been mentioned as "Not less than 80% (Q) in 30minutes", "NLT 75% in 40 minutes" and "NLT 80% (Q) in 45 minutes" on different instances within the application dossier. Please justify.	**Typographical Mistake.**	
	vi. 3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Ref. Lot. No. F048W0 has been submitted.	
	vii. Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.	
	viii. Please justify (with supporting evidence) the manufacturing of a		

	Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023), as mentioned in your application dossiers. ix. Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	**The Firm has submitted that their Capsule filling machine capacity is 10,000 capsules per hour. Blister machine capacity is 1200-1500 strokes and each stroke contains 03 blisters or 3600 blisters/hour. Machine cleaning process is also limited due to same API used in the manufactured batches. 18 batches become 27000 capsules and 3857 blisters.** Gabica 25mg Capsule, Batch No. 000850.	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Rationale for manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023) and their placing in Stability Chambers.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

531.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22157 dated 08 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 30-08-2023

		(Challan / Receipt # 812330476)
	The proposed proprietary name / brand name	**GABEK 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin … 50mg (BP Specifications)
	Pharmacotherapeutic Group of (API)	N02BF02, Gabapentinoids / antiepileptic agents.
	Pharmaceutical form of applied drug	White to off-white powder filled in Hard Gelatin Capsule Shell.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA 50mg Capsules of UPJOHN (USFDA Approved).
	For generic drugs (me-too status)	GABICA 50mg Capsules by M/s. Getz Pharma (Pvt.) Ltd.
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd. Platinum Techno Park haware, Bhagwan Mahaveer Road, Sector 30, Vashi, Navi Mumbai, Maharashtra 400703, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GABICA 50mg Capsule manufactured by M/s Getz

		Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GABICA 50mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., India.		
API Lot No.	PPR/21010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	03-02-2023	03-02-2023	03-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of commercial invoice attested by AD I&E DRAP, Islamabad has been submitted for Pregabalin USP Batch No. PPR/21010 for M/s Panacea Pharma, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

	Deficiencies / Observations	Response of the Firm
i.	The submitted Real Time Stability Study Data of Drug Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*** No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product upon completion of 01 Year.
ii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The submitted GMP Certificate was valid till 02-11-2023.**
iii.	Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
iv.	2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.**
v.	The dissolution specifications of FPP have been mentioned as "Not less than 80% (Q) in 30minutes", "NLT 75% in 40 minutes" and "NLT 80% (Q) in 45 minutes" on different instances within the application dossier. Please justify.	**Typographical Mistake.**
vi.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the	COA of Working Standard referred against USP Ref. Lot. No. F048W0 has been submitted.

	mentioned Working Standard against the Reference Standard.	
vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March2015 has been submitted.
viii.	Please justify (with supporting evidence) the manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023), as mentioned in your application dossiers.	**The Firm has submitted that their Capsule filling machine capacity is 10,000 capsules per hour. Blister machine capacity is 1200-1500 strokes and each stroke contains 03 blisters or 3600 blisters/hour. Machine cleaning process is also limited due to same API used in the manufactured batches. 18 batches become 27000 capsules and 3857 blisters.** Gabica 50mg Capsule, Batch No. 0001050
ix.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Rationale for manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023) and their placing in Stability Chambers.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

532.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22158 dated 08 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 30-08-2023 (Challan / Receipt # 6569058897)
	The proposed proprietary name / brand name	**GABEK 75mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin … 75mg (BP Specifications)
	Pharmacotherapeutic Group of (API)	N02BF02, Gabapentinoids / antiepileptic agents.
	Pharmaceutical form of applied drug	White to off-white powder filled in Hard Gelatin Capsule Shell.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA 75mg Capsules of UPJOHN (USFDA Approved).
	For generic drugs (me-too status)	GABICA 75mg Capsules by M/s. Getz Pharma (Pvt.) Ltd.
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd. Platinum Techno Park haware, Bhagwan Mahaveer Road, Sector 30, Vashi, Navi Mumbai, Maharashtra 400703, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GABICA 75mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GABICA 75mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., India.		
API Lot No.	PPR/21010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	03-02-2023	03-02-2023	03-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of commercial invoice attested by AD I&E DRAP, Islamabad has been submitted for Pregabalin USP Batch No. PPR/21010 for M/s Panacea Pharma, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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

Deficiencies / Observations	Response of the Firm
i. The submitted Real Time Stability Study Data of Drug Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH for 24Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*** No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product upon completion of 01 Year.
ii. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The submitted GMP Certificate was valid till 02-11-2023.**
iii. Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
iv. 2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.** **Typographical Mistake.**

v.	The dissolution specifications of FPP have been mentioned as "Not less than 80% (Q) in 30minutes", "NLT 75% in 40 minutes" and "NLT 80% (Q) in 45 minutes" on different instances within the application dossier. Please justify.		
vi.	3.2.P.6 It has been mentioned that Working Standard has been used for analyticaltesting. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Ref. Lot. No. F048W0 has been submitted.	
vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.	
viii.	Please justify (with supporting evidence) the manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023), as mentioned in your application dossiers.	**The Firm has submitted that their Capsule filling machine capacity is 10,000 capsules per hour. Blister machine capacity is 1200-1500 strokes and each stroke contains 03 blisters or 3600 blisters/hour. Machine cleaning process is also limited due to same API used in the manufactured batches. 18 batches become 27000 capsules and 3857 blisters.** Gabica 75mg Capsule, Batch No. 0006390	
ix.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.		

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Rationale for manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023) and their placing in Stability Chambers.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

533.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.

	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22159 dated 08 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 30-08-2023 (Challan / Receipt # 0457921987)
	The proposed proprietary name / brand name	**GABEK 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin … 100mg (BP Specifications)
	Pharmacotherapeutic Group of (API)	N02BF02, Gabapentinoids / antiepileptic agents.
	Pharmaceutical form of applied drug	White to off-white powder filled in Hard Gelatin Capsule Shell.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA 100mg Capsules of UPJOHN (USFDA Approved).
	For generic drugs (me-too status)	GABICA 100mg Capsules by M/s. Getz Pharma (Pvt.) Ltd.
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd. Platinum Techno Park haware, Bhagwan Mahaveer Road, Sector 30, Vashi, Navi Mumbai, Maharashtra 400703, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GABICA 100mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GABICA 100mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., India.		
API Lot No.	PPR/21010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	03-02-2023	03-02-2023	03-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of commercial invoice attested by AD I&E DRAP, Islamabad has been submitted for Pregabalin USP Batch No. PPR/21010 for M/s Panacea Pharma, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	Response of the Firm
i. The submitted Real Time Stability Study Dataof Drug Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*** No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product upon completion of 01 Year.
ii. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The submitted GMP Certificate was valid till 02-11-2023.** Submitted.

iii.	Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	**Typographical Mistake.**
iv.	2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.**
v.	The dissolution specifications of FPP have been mentioned as "Not less than 80% (Q) in 30minutes", "NLT 75% in 40 minutes" and "NLT 80% (Q) in 45 minutes" on different instances within the application dossier. Please justify.	
vi.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Ref. Lot. No. F048W0 has been submitted.
vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March2015 has been submitted.
viii.	Please justify (with supporting evidence) the manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023), as mentioned in your application dossiers.	**The Firm has submitted that their Capsule filling machine capacity is 10,000 capsules per hour. Blister machine capacity is 1200-1500 strokes and each stroke contains 03 blisters or 3600 blisters/hour. Machine cleaning process is also limited due to same API used in the manufactured batches. 18 batches become 27000 capsules and 3857 blisters.** Gabica 100mg Capsule, Batch No. 000850.
ix.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Rationale for manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023) and their placing in Stability Chambers.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

534.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**

	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22160 dated 08 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 30-08-2023 (Challan / Receipt # 80393461730)
	The proposed proprietary name / brand name	**GABEK 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin … 150mg (BP Specifications)
	Pharmacotherapeutic Group of (API)	N02BF02, Gabapentinoids / antiepileptic agents.
	Pharmaceutical form of applied drug	White to off-white powder filled in Hard Gelatin Capsule Shell.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA 150mg Capsules of UPJOHN (USFDA Approved).
	For generic drugs (me-too status)	GABICA 150mg Capsules by M/s. Getz Pharma (Pvt.) Ltd.
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd. Platinum Techno Park haware, Bhagwan Mahaveer Road, Sector 30, Vashi, Navi Mumbai, Maharashtra 400703, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GABICA 150mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GABICA 150mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., India.		
API Lot No.	PPR/21010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	03-02-2023	03-02-2023	03-02-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of commercial invoice attested by AD I&E DRAP, Islamabad has been submitted for Pregabalin USP Batch No. PPR/21010 for M/s Panacea Pharma, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
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Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

Deficiencies / Observations	Response of the Firm
i. The submitted Real Time Stability Study Data of Drug Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*** No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product upon completion of 01 Year.

ii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The submitted GMP Certificate was valid till 02-11-2023.**
iii.	Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
iv.	2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.**
v.	The dissolution specifications of FPP have been mentioned as "Not less than 80% (Q) in 30minutes", "NLT 75% in 40 minutes" and "NLT 80% (Q) in 45 minutes" on different instances within the application dossier. Please justify.	**Typographical Mistake.**
vi.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Ref. Lot. No. F048W0 has been submitted.
vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March2015 has been submitted.
viii.	Please justify (with supporting evidence) the manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023), as mentioned in your application dossiers.	**The Firm has submitted that their Capsule filling machine capacity is 10,000 capsules per hour. Blister machine capacity is 1200-1500 strokes and each stroke contains 03 blisters or 3600 blisters/hour. Machine cleaning process is also limited due to same API used in the manufactured batches. 18 batches become 27000 capsules and 3857 blisters.**
ix.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Gabica 150mg Capsule, Batch No. 000134.

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Rationale for manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023) and their placing in Stability Chambers.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.		
535.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22161 dated 08 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 31-08-2023 (Challan / Receipt # 7363045187)
	The proposed proprietary name / brand name	**GABEK 300mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin … 300mg (BP Specifications)
	Pharmacotherapeutic Group of (API)	N02BF02, Gabapentinoids / antiepileptic agents.
	Pharmaceutical form of applied drug	White to off-white powder filled in Hard Gelatin Capsule Shell.
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA 300mg Capsules of UPJOHN (USFDA Approved).
	For generic drugs (me-too status)	GABICA 300mg Capsules by M/s. Getz Pharma (Pvt.) Ltd.
	Name and address of API manufacturer.	M/s Progress Life Sciences Pvt. Ltd. Platinum Techno Park haware, Bhagwan Mahaveer Road, Sector 30, Vashi, Navi Mumbai, Maharashtra 400703, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GABICA 300mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GABICA 300mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Progress Life Sciences Pvt. Ltd., India.		
API Lot No.	PPR/21010		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	02-2023	02-2023	02-2023

Date of Initiation	03-02-2023	03-02-2023	03-02-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of commercial invoice attested by AD I&E DRAP, Islamabad has been submitted for Pregabalin USP Batch No. PPR/21010 for M/s Panacea Pharma, Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	Response of the Firm
i. The submitted Real Time Stability Study Data of Drug Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.***	**Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product upon completion of 01 Year.**

	No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	
ii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The submitted GMP Certificate was valid till 02-11-2023.**
iii.	Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
iv.	2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.**
v.	The dissolution specifications of FPP have been mentioned as "Not less than 80% (Q) in 30minutes", "NLT 75% in 40 minutes" and "NLT 80% (Q) in 45 minutes" on different instances within the application dossier. Please justify.	**Typographical Mistake.**
vi.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Ref. Lot. No. F048W0 has been submitted.
vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March2015 has been submitted.
viii.	Please justify (with supporting evidence) the manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023), as mentioned in your application dossiers.	**The Firm has submitted that their Capsule filling machine capacity is 10,000 capsules per hour. Blister machine capacity is 1200-1500 strokes and each stroke contains 03 blisters or 3600 blisters/hour. Machine cleaning process is also limited due to same API used in the manufactured batches. 18 batches become 27000 capsules and 3857 blisters.**
ix.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Gabica 300mg Capsule, Batch No. 000423

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**

• **Rationale for manufacturing of a Total of 18 Batches (03 Trials of each strength) on a single day (i.e. 02-02-2023) and their placing in Stability Chambers.** **Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.**		
536.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - **i. Tablet (General) Section.** **ii.** Capsule (General) Section. **iii.** Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16143 dated 26 JUN 2023
	Details of fee submitted	PKR 30,000/- Dated 30-05-2023 (Challan / Receipt # 192110675946)
	The proposed proprietary name / brand name	**PAROXEPINE 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Paroxetine (as hydrochloride hemihydrate) … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	N06AB05, Selective serotonin reuptake inhibitors
	Pharmaceutical form of applied drug	White to off-white, round, unscored, biconvex, film coated tablet.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SEROXAT 20mg Tablets, MHRA UK Approved.
	For generic drugs (me-too status)	SEROXAT 20mg Tablets by M/s GSK Pakistan Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against SEROXAT 20mg Tablets by M/s GSK Pakistan Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against SEROXAT 20mg Tablets by M/s GSK Pakistan Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China.
API Lot No.	5820070208
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 Months Accelerated: 6 Months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T01P	T02P	T03P
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	04-10-2022	04-10-2022	04-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad has been submitted. **However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**The Firm has submitted that their HPLC system is not 21 CFR compliant.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	**Response of the Firm**
i. In the applied formulation, please justify the use of Methanol along with Isopropyl alcohol, Talcum and Lactose with supporting evidence. As the same has not been mentioned ininnovator / reference product formulation therefore, please submit compatibility studies of the same as excipients in the appliedformulation.	The firm has referred to the Hand Book of Pharmaceutical Excipients and their Stability Study Data Results.
ii. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin has not been submitted.** Submitted.

iii. Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	**No response has been submitted.**
iv. Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad. However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP. Please provide evidence of removal of condition / utilization approval for the same.	
v. 2.3.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Reference Batch No. 5817060201 has been submitted.
vi. 2.3.P.8.2 The Container closure system has been mentioned as "Alu-PVC Blister", whereas the same has been mentioned as "Alu-Alu Blister" on separate instances in the same application, please clarify.	**Typographical Mistake.**
vii. Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP Studies.	Seroxat 20mg Tablet, Batch No. 140331

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad. However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP. Please provide evidence of removal of condition / utilization approval for the same.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

537.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: -

		i. Tablet (General) Section. **ii.** Capsule (General) Section. **iii.** Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16144 dated 26 JUN 2023
	Details of fee submitted	PKR 30,000/- Dated 07-06-2023 (Challan / Receipt # 2237392214)
	The proposed proprietary name / brand name	**PAROXEPINE 12.5mg CR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric film coated controlled release tablet contains Paroxetine (as hydrochloride hemihydrate) … 12.5mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	N06AB05, Selective serotonin reuptake inhibitors
	Pharmaceutical form of applied drug	White to off-white, round, unscored, biconvex, enteric film coated controlled release tablet.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PAXIL 12.5mg CR Tablets, USFDA Approved.
	For generic drugs (me-too status)	SEROXAT 12.5mg CR Tablets of GSK Pakistan Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of drug

	(Conditions & duration of Stability studies)	substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against SEROXAT 12.5mg CR Tablets of GSK Pakistan Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against SEROXAT 12.5mg CR Tablets of GSK Pakistan Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China.		
API Lot No.	5820070208		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	10-10-2022	10-10-2022	10-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad has been submitted. **However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**The Firm has submitted that their HPLC system is not 21 CFR compliant.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

	Deficiencies / Observations	Response of the Firm
i.	In the applied formulation, please justify the use of Methanol along with Castor Oil, Titanium dioxide, Isopropyl alcohol and Polyethylene Glycol with supporting evidence. As the same has not been mentioned in innovator / reference product formulation therefore, please submit compatibility studies of the same as excipients in the applied formulation.	The firm has referred to the Hand Book of Pharmaceutical Excipients and their Stability Study Data Results.
ii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin has not been submitted.**
iii.	Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
iv.	Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad. However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP. Please provide evidence of removal of condition / utilization approval for the same.	**No response has been submitted.**
v.	2.3.P.6 It has been mentioned that Working Standard has been used for analytical testing.	

	Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Reference Batch No. 5817060201 has been submitted.
vi.	2.3.P.8.2 The Container closure system has been mentioned as "Alu-PVC Blister", whereas the same has been mentioned as "Alu-Alu Blister" on separate instances in the same application, please clarify.	**Typographical Mistake.**
vii.	2.3.R.2 The Column Specifications have been mentioned as "4.6mm × 2.5cm: 5-µm packing L13" whereas the USP specifies the same as "4.6-mm × 25-cm; 5-µm packing L13". Please clarify.	**Typographical Mistake.**
viii.	Please provide evidence of Reference / Innovator's Packs (along with Batch details) used for Pharmaceutical Equivalence and CDP Studies for each strength	Seroxat 12.5mg CR Tablet

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad. However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP. Please provide evidence of removal of condition / utilization approval for the same.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

538.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - **i. Tablet (General) Section.** **ii.** Capsule (General) Section. **iii.** Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16145 dated 26 JUN 2023
	Details of fee submitted	PKR 30,000/- Dated 07-06-2023 (Challan / Receipt # 553022394)
	The proposed proprietary name / brand name	**PAROXEPINE 25mg CR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric film coated controlled release tablet contains Paroxetine (as hydrochloride hemihydrate) … 25mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	N06AB05, Selective serotonin reuptake inhibitors
	Pharmaceutical form of applied drug	White to off-white, round, unscored, biconvex, enteric film coated controlled release tablet.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PAXIL 25mg CR Tablets, USFDA Approved.
	For generic drugs (me-too status)	SEROXAT 25mg CR Tablets of GSK Pakistan Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against SEROXAT 25mg CR Tablets of GSK Pakistan Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against SEROXAT 25mg CR Tablets of GSK Pakistan Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China.		
API Lot No.	5820070208		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	10-10-2022	10-10-2022	10-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad has been submitted. **However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP.**
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

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

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

Deficiencies / Observations	Response of the Firm
i. In the applied formulation, please justify the useof Methanol along with Castor Oil, Titanium dioxide, Isopropyl alcohol and Polyethylene Glycol with supporting evidence. As the same has not been mentioned in innovator / reference product formulation therefore, please submit compatibility studies of the same as excipients in the applied formulation.	The firm has referred to the Hand Book of Pharmaceutical Excipients and their Stability Study Data Results.
ii. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin has not been submitted.**
iii. Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
iv. Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad. However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP. Please provide evidence of removal of condition / utilization approval for the same.	**No response has been submitted.**
v. 2.3.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard referred against USP Reference Batch No. 5817060201 has been submitted.
vi. 2.3.P.8.2 The Container closure system has been mentioned as "Alu-PVC Blister", whereas the same has been mentioned as "Alu-Alu Blister" on separate instances in the same application, please clarify.	**Typographical Mistake.**

vii.	2.3.R.2 The Column Specifications have been mentioned as "4.6mm × 2.5cm: 5-µm packing L13" whereas the USP specifies the same as "4.6-mm × 25-cm; 5-µm packing L13". Please clarify.	**Typographical Mistake.**
viii.	Please provide evidence of Reference / Innovator's Packs (along with Batch details) used for Pharmaceutical Equivalence and CDP Studies for each strength	Seroxat 25mg CR Tablet

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Copy of Clearance (vide No. 3607-I&E dated 22 DEC 2020) by AD I&E DRAP, Islamabad has been submitted for Paroxetine HCl Batch No. 5820070208 for M/s Panacea Pharma, Islamabad. However, the same had been issued conditionally with "Utilization Restriction" till submission of valid GMP. Please provide evidence of removal of condition / utilization approval for the same.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

539.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19867 dated 10 AUG 2023
	Details of fee submitted	PKR 30,000/- Dated 26-07-2023 (Challan / Receipt # 1195693795)
	The proposed proprietary name / brand name	**GISEK 20mg Capsule**
	Strength / concentration of drug of	Each capsule contains:

	Active Pharmaceutical ingredient (API) per unit	Enteric coated pellets of omeprazole equivalent to omeprazole … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	A02BC01, Proton pump inhibitors
	Pharmaceutical form of applied drug	White to off-white colored spherical pellets filled in Hard Gelatin Capsule Shell.
	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	Omeprazole 20 mg Gastro-resistant Capsules, MHRA Approved.
	For generic drugs (me-too status)	RISEK Capsule 20mg by M/s Getz Pharma.
	Name and address of API manufacturer.	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RISEK Capsule 20mg by M/s Getz Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit).

		Firm has submitted CDP results of their product against RISEK Capsule 20mg by M/s Getz Pharma in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	OMP1217		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2,000 Capsules	2,000 Capsules	2,000 Capsules
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	15-12-2022	15-12-2022	15-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 802848 dated 03-Jun-22 (for local purchase) of API from Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	Response of the Firm

i.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
ii.	2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake**
iii.	2.3.P.5.5 In Characterization of Impurities it has been mentioned that *"All impurities specified in the USP monograph of the latest edition of pharmacopeia are included in the finished products specifications",* however, no such test on impurities has been performed in submitted finished product testing. Please justify.	**FPP Manufacturer have not performed Impurity Studies on Finished Product.**
iv.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard against USP Ref. Lot. No. R065NO has been submitted.
v.	3.2.P.5.6 Enclosed Analytical Report of Working Standard states its Manufacturer as "Surge Laboratories", please clarify.	**Clarification Not submitted.**
vi.	3.2.P.8.3 In submitted Stability Study Summary Sheets (Real Time) for Batch No. T002 of Gisek 20mg Capsules, the Assay result for '0 Month' time interval is mentioned as "90.0% - 110.0%". Please justify.	**Typographical Mistake.** **Correct results are 101.51%.**
vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.
viii.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Risek 20mg Capsule, Batch No. C03038

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Scientific Rationale for not performing Impurity Studies on Finished Product by FPP Manufacturer.**
- **3.2.P.5.6 Enclosed Analytical Report of Working Standard states its Manufacturer as "Surge Laboratories", please clarify.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

540.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**

	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19868 dated 10 AUG 2023
	Details of fee submitted	PKR 30,000/- Dated 26-07-2023 (Challan / Receipt # 8499679432)
	The proposed proprietary name / brand name	**GISEK 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric coated pellets of omeprazole equivalent to omeprazole … 40mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	A02BC01, Proton pump inhibitors
	Pharmaceutical form of applied drug	White to off-white colored spherical pellets filled in Hard Gelatin Capsule Shell.
	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	Omeprazole 40 mg Gastro-resistant Capsules, MHRA Approved.
	For generic drugs (me-too status)	RISEK Capsule 40mg by M/s Getz Pharma.
	Name and address of API manufacturer.	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

		and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RISEK Capsule 40mg by M/s Getz Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against RISEK Capsule 40mg by M/s Getz Pharma in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	OMP1217		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2,000 Capsules	2,000 Capsules	2,000 Capsules
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	15-12-2022	15-12-2022	15-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 802848 dated 03-Jun-22 (for local purchase) of API from Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	Response of the Firm
i. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
ii. 2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake**
iii. 2.3.P.5.5 In Characterization of Impurities it has been mentioned that *"All impurities specified in the USP monograph of the latest edition of pharmacopeia are included in the finished products specifications",* however, no such test on impurities has been performed in submitted finished product testing. Please justify.	**FPP Manufacturer have not performed Impurity Studies on Finished Product.**
iv. 3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard against USP Ref. Lot. No. R065NO has been submitted.

v.	3.2.P.5.6 Enclosed Analytical Report of Working Standard states its Manufacturer as "Surge Laboratories", please clarify.	**Clarification Not submitted.**
vi.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.
vii.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Risek 40mg Capsule, Batch No. C04023.

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Scientific Rationale for not performing Impurity Studies on Finished Product by FPP Manufacturer.**
- **3.2.P.5.6 Enclosed Analytical Report of Working Standard states its Manufacturer as "Surge Laboratories", please clarify.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

541.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - **i. Tablet (General) Section.** **ii.** Capsule (General) Section. **iii.** Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23764 dated 21 NOV 2023
	Details of fee submitted	PKR 30,000/- Dated 14-11-2023 (Challan / Receipt # 108659222551)
	The proposed proprietary name / brand name	**SULPIN 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each un-coated tablet contains Levosulpiride … 25mg (Innovator's Specifications)

	Pharmacotherapeutic Group of (API)	N05AL07, Antipsychotics, Benzamides.
	Pharmaceutical form of applied drug	Light green colored round biconvex core tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ARISTO 25mg Tablets (Levosulpiride), AIFA Italy Approved.
	For generic drugs (me-too status)	SULVORID 25mg Tablets of M/s High-Q Pharma.
	Name and address of API manufacturer.	M/s Varahi International opp: Naroda Rly Station, N.H. No. 8, Naroda City, Ahmedabad – 382 330, Gujarat State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against SULVORID 25mg Tablets of M/s High-Q Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against SULVORID 25mg Tablets of M/s High-Q Pharma in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Varahi International opp: Naroda Rly Station, N.H. No. 8, Naroda City, Ahmedabad – 382 330, Gujarat State, India.		
API Lot No.	31L01Z2122-012		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	24-04-2023	24-04-2023	24-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of Commercial Invoice No. TM/144/21-22 dated 27-07-2021 signed by AD I&E DRAP, Islamabad has been submitted for Levosulpiride Batch No. 31L01Z2122-12 for M/s Panacea Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**The Firm has submitted that their HPLC system is not 21 CFR compliant.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	Response of the Firm

i.	Please provide undertakings / commitments as required in sections **1.5.15 − 1.5.20**. The submitted document is without signatures.	Submitted.
ii.	Information submitted in 2.3.S.7.1 a) statesthat the Real Time Stability Study of Drug Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*** No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product upon completion of 01 Year.
iii.	Information provided in 2.3.P.5.4 Batch Analysis a) Description of Batches specifies Date of manufacturing of Batch Nos. T001, T002 and T003 as *"03-2025"*. Please justify.	**Typographical Mistake**
iv.	Please provide approval of API/ DML of API manufacturer issued by concerned regulatory authority of country of origin.	Approval of API/ DML of API manufacturer issued by concerned regulatory authority of country of origin **has not been submitted.**
v.	Finished Product Specifications have been claimed as that of "Innovator's Specifications", however, in section 3.2.P.5.1 the same have been claimed as "In-House". Please justify.	**Typographical Mistake.**
vi.	Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
vii.	2.3.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the	Firm has submitted that they had used Secondary Working Standard provided by the supplier and

mentioned Working Standard against the Reference Standard.	claimed there was no availability of Primary Working Standard.
viii. Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP Studies for each strength.	SULVORID 25mg Tablet, Batch No. 2SV263.

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

542.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - **i. Tablet (General) Section.** **ii.** Capsule (General) Section. **iii.** Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23765 dated 21 NOV 2023
	Details of fee submitted	PKR 30,000/- Dated 14-11-2023 (Challan / Receipt # 034388153)
	The proposed proprietary name / brand name	**SULPIN 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each un-coated tablet contains Levosulpiride … 50mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	N05AL07, Antipsychotics, Benzamides.
	Pharmaceutical form of applied drug	Light blue colored round biconvex un-coated tablet
	Reference to Finished product specifications	Innovator's Specifications

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ARISTO 50mg Tablets (Levosulpiride), AIFA Italy Approved.
	For generic drugs (me-too status)	SULVORID 50mg Tablets of M/s High-Q Pharma.
	Name and address of API manufacturer.	M/s Varahi International opp: Naroda Rly Station, N.H. No. 8, Naroda City, Ahmedabad – 382 330, Gujarat State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against SULVORID 50mg Tablets of M/s High-Q Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against SULVORID 50mg Tablets of M/s High-Q Pharma in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Varahi International opp: Naroda Rly Station, N.H. No. 8, Naroda City, Ahmedabad – 382 330, Gujarat State, India.
API Lot No.	31L01Z2122-012

Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	04-2023	04-2023	04-2023
Date of Initiation	24-04-2023	24-04-2023	24-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Documents regarding Loan of API have not been submitted.** Copy of Commercial Invoice No. TM/144/21-22 dated 27-07-2021 signed by AD I&E DRAP, Islamabad has been submitted for Levosulpiride Batch No. 31L01Z2122-12 for M/s Panacea Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**The Firm has submitted that their HPLC system is not 21 CFR compliant.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

Deficiencies / Observations	Response of the Firm
i. Please provide undertakings / commitments as required in sections **1.5.15 – 1.5.20**. The submitted document is without signatures.	Submitted.
ii. Information submitted in 2.3.S.7.1 a) statesthat the Real Time Stability Study of Drug	Firm has submitted that they will submit 01 Year Real Time Stability Data with Degradation

	Substance has been conducted at 25°C ± 2°C / 60% ± 5% RH for 24 Months. The Registration Board in its 290th Meeting had decided as follows: • ***In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*** • ***Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*** No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	Studies in the Finished Pharmaceutical Product upon completion of 01 Year.
iii.	Information provided in 2.3.P.5.4 Batch Analysis a) Description of Batches specifies Date of manufacturing of Batch Nos. T001, T002 and T003 as *"03-2025"*. Please justify.	**Typographical Mistake**
iv.	Please provide approval of API/ DML of API manufacturer issued by concerned regulatory authority of country of origin.	Approval of API/ DML of API manufacturer issued by concerned regulatory authority of country of origin **has not been submitted.**
v.	Finished Product Specifications have been claimed as that of "Innovator's Specifications", however, in section 3.2.P.5.1 the same have been claimed as "In-House". Please justify.	**Typographical Mistake.**
vi.	Please provide Letter and agreement of loan of API, specifying the quantity of borrowed API.	Submitted.
vii.	2.3.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	Firm has submitted that they had used Secondary Working Standard provided by the supplier and claimed there was no availability of Primary Working Standard.
viii.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP Studies for each strength.	SULVORID 50mg Tablet, Batch No. 5SV123.

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Real Time Stability Data with Degradation Studies in the Finished Pharmaceutical Product.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

543.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16142 dated 26 JUN 2023
	Details of fee submitted	PKR 30,000/- Dated 21-06-2023 (Challan / Receipt # 629741946)
	The proposed proprietary name / brand name	**ESSOP 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric coated pellets of esomeprazole magnesium trihydrate equivalent to esomeprazole … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	A02BC05, Proton pump inhibitors
	Pharmaceutical form of applied drug	White to off-white colored pellets filled in Blue/blue Hard Gelatin Capsule Shell.
	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	NEXIUM 20mg & 40mg delayed release capsules, USFDA Approved.

	For generic drugs (me-too status)	NEXUM 20mg Capsule, Getz Pharma, Reg. No. 033890.
	Name and address of API manufacturer.	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against NEXUM 20mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against NEXUM 20mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
API Lot No.	EMZ046479
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 Months

	Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2,000 Capsules	2,000 Capsules	2,000 Capsules
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	05-12-2022	05-12-2022	05-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 802677 dated 16-May-22 (for local purchase) of API from Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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

	Deficiencies / Observations	Response of the Firm
i.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
ii.	2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.**
iii.	2.3.S.4.5 Justification of Specifications has been provided for "Fluconazole". Please justify.	**Typographical Mistake.**

	iv. 2.3.S.5 Specifications of primary / secondary reference standard has been provided for "Fluconazole". Please justify.	
	v. 2.3.P.5.5 In Characterization of Impurities it has been mentioned that *"All impurities specified in the USP monograph of the latest edition of pharmacopeia are included in the finished products specifications"*, however, no such test on impurities has been performed in submitted finished product testing. Please justify.	**The Firm has submitted that they have not performed Impurity Testing on Finished Pharmaceutical Product.**
	vi. 3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	**COA of Working Standard OMP/2202022 from Surge Laboratories has been submitted.**
	vii. Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.
	viii. Please provide evidence ofReference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Nexum 20mg Capsule, Batch No. 000860.

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Scientific Rationale for not performing Impurity Testing on Finished Pharmaceutical Product by FPP Manufacturer.**
- **Scientific Rationale for using Working Standard from Surge Laboratories – a third party.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

544.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.

	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16136 dated 26 JUN 2023
	Details of fee submitted	PKR 30,000/- Dated 21-06-2023 (Challan / Receipt # 7411633221)
	The proposed proprietary name / brand name	**ESSOP 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric coated pellets of esomeprazole magnesium trihydrate equivalent to esomeprazole … 40mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	A02BC05, Proton pump inhibitors
	Pharmaceutical form of applied drug	White to off-white colored pellets filled in Blue/blue Hard Gelatin Capsule Shell.
	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	NEXIUM 20mg & 40mg delayed release capsules, USFDA Approved.
	For generic drugs (me-too status)	NEXUM 40mg Capsule, Getz Pharma, Reg. No. 033891.
	Name and address of API manufacturer.	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against NEXUM 40mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against NEXUM 40mg Capsule manufactured by M/s Getz Pharma (Pvt.) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.		
API Lot No.	EMZ046479		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2,000 Capsules	2,000 Capsules	2,000 Capsules
Manufacturing Date	12-2022	12-2022	12-2022
Date of Initiation	05-12-2022	05-12-2022	05-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 802677 dated 16-May-22 (for local purchase) of API from Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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

Deficiencies / Observations	Response of the Firm
i. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
ii. 2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake.**
iii. 2.3.S.4.5 Justification of Specifications has been provided for "Fluconazole". Please justify.	**Typographical Mistake.**
iv. 2.3.S.5 Specifications of primary / secondary reference standard has been provided for "Fluconazole". Please justify.	**Typographical Mistake.**
v. 2.3.P.5.5 In Characterization of Impurities it has been mentioned that *"All impurities specified in the USP monograph of the latest edition of pharmacopeia areincluded in the finished products specifications",* however, no such test on impurities has been performed in submitted finished product testing. Please justify.	**The Firm has submitted that they have not performed Impurity Testing on Finished Pharmaceutical Product.**
vi. 3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	**COA of Working Standard OMP/2202022 from Surge Laboratories has been submitted.**

vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted. Nexum 40mg Capsule, Batch No. C01850.
viii.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Scientific Rationale for not performing Impurity Testing on Finished Pharmaceutical Product by FPP Manufacturer.**
- **Scientific Rationale for using Working Standard from Surge Laboratories – a third party.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

545.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26813 dated 10 NOV 2023
	Details of fee submitted	PKR 30,000/- Dated 16-10-2023 (Challan / Receipt # 796927073)
	The proposed proprietary name / brand name	**DUTAX 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric coated pellets of duloxetine hydrochloride equivalent to duloxetine … 20mg (USP Specifications)

	Pharmacotherapeutic Group of (API)	N06AX21, Other antidepressants
	Pharmaceutical form of applied drug	White to off-white colored spherical pellets filled in Hard Gelatin Capsule Shell.
	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	CYMBALTA (20mg, 30mg, 60mg) delayed-release capsules, USFDA Approved
	For generic drugs (me-too status)	LYTA 20mg Capsule by M/s Getz Pharma (Reg. No. 066916).
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle , Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against LYTA 20mg Capsule by M/s Getz Pharma byperforming quality tests (Identification, Assay, Dissolution, andUniformity of dosage unit). Firm has submitted CDP results of their product against LYTA 20mg Capsule by M/s Getz Pharma in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd., Islamabad.		
API Lot No.	DXT303		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	22-06-2023	22-06-2023	22-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 903020 dated 14-Jun-23 (for local purchase) of API from Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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

Deficiencies / Observations	Response of the Firm
i. Please provide approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.

	ii.	2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake**	
	iii.	2.3.R.2 In Analytical Procedures and Validation Information for Drug Product, Analytical Method for Testing of "Esomeprazole Capsule" has been submitted. Please justify.	**Typographical Mistake**	
	iv.	3.2.S.7.1 In Stability Summary and Conclusion, it has been mentioned that the drug substance is *"found stable under long term conditions temperature 25C + 2C and humidity 60 +5%) for a period of 3 years".* Please justify.	**Typographical Mistake**	
	v.	Please provide stability results observed for the Accelerated and Long-term studies of 03 stability batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for 06th Month Time Interval for each strength.	**Not submitted. 6th Month Stability Study Schedule Date is 31/12/2023.**	
	vi.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard against USP Ref. Lot. No. R043X0 has been submitted.	
	vii.	Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.	
	viii.	Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Lyta 20mg Capsule, Batch No. 057036	
	ix.	Please provide Commitments / Undertakings as required in Sections 1.5.15 – 1.5.20. The submitted document is without signatures.	Submitted.	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Stability results observed for the Accelerated and Long-term studies of 03 stability batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for 06th Month Time Interval.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.		
546.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26814 dated 10 NOV 2023
	Details of fee submitted	PKR 30,000/- Dated 16-10-2023 (Challan / Receipt # 550771960072)
	The proposed proprietary name / brand name	**DUTAX 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric coated pellets of duloxetine hydrochloride equivalent to duloxetine … 30mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	N06AX21, Other antidepressants
	Pharmaceutical form of applied drug	White to off-white colored spherical pellets filled in Hard Gelatin Capsule Shell.
	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	CYMBALTA (20mg, 30mg, 60mg) delayed-release capsules, USFDA Approved
	For generic drugs (me-too status)	LYTA 30mg Capsule by M/s Getz Pharma (Reg. No. 066917).
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle , Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure,

		general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against LYTA 30mg Capsule by M/s Getz Pharma byperforming quality tests (Identification, Assay, Dissolution, andUniformity of dosage unit). Firm has submitted CDP results of their product against LYTA 30mg Capsule by M/s Getz Pharma in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd., Islamabad.		
API Lot No.	DXT303		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	06-2023	06-2023	06-2023

Date of Initiation	22-06-2023	22-06-2023	22-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 903020 dated 14-Jun-23 (for local purchase) of API from Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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

Deficiencies / Observations	Response of the Firm
i. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
ii. 2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake**
iii. 2.3.R.2 In Analytical Procedures and Validation Information for Drug Product, Analytical Method for Testing of "Esomeprazole Capsule" has been submitted. Please justify.	**Typographical Mistake**
iv. 3.2.S.7.1 In Stability Summary and Conclusion, it has been mentioned that the drug substance is *"found stable under long term conditions temperature 25C + 2Cand humidity 60 +5%) for a period of 3 years"*. Please justify.	**Typographical Mistake**

	v. Please provide stability results observed for the Accelerated and Long-term studies of 03 stability batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for 06th Month Time Interval for each strength.	**Not submitted. 6th Month Stability Study Schedule Date is 31/12/2023.**	
	vi. 3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard against USP Ref. Lot. No. R043X0 has been submitted.	
	vii. Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.	
	viii. Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Lyta 30mg Capsule, Batch No. 150C34	
	ix. Please provide Commitments / Undertakings as required in Sections 1.5.15 – 1.5.20. The submitted document is without signatures.	Submitted.	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Stability results observed for the Accelerated and Long-term studies of 03 stability batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for 06th Month Time Interval.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

547.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000955) issued w.e.f. 28-04-2022.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 1-8/2019-Lic dated 29th April, 2022 contains section approval for: - i. Tablet (General) Section. **ii. Capsule (General) Section.** iii. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26815 dated 10 NOV 2023
	Details of fee submitted	PKR 30,000/- Dated 16-10-2023 (Challan / Receipt # 2491303955)
	The proposed proprietary name / brand name	**DUTAX 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Enteric coated pellets of duloxetine hydrochloride equivalent to duloxetine … 60mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	N06AX21, Other antidepressants
	Pharmaceutical form of applied drug	White to off-white colored spherical pellets filled in Hard Gelatin Capsule Shell.
	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	CYMBALTA (20mg, 30mg, 60mg) delayed-release capsules, USFDA Approved
	For generic drugs (me-too status)	LYTA 60mg Capsule by M/s Getz Pharma (Reg. No. 066918).
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle , Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against LYTA 60mg Capsule by M/s Getz Pharma byperforming quality tests (Identification, Assay, Dissolution, andUniformity of dosage unit). Firm has submitted CDP results of their product against LYTA 60mg Capsule by M/s Getz Pharma in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd., Islamabad.		
API Lot No.	DXT303		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	06-2023	06-2023	06-2023
Date of Initiation	22-06-2023	22-06-2023	22-06-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 903020 dated 14-Jun-23 (for local purchase) of API from Vision Pharma, Islamabad has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not submitted certificate of 21 CFR compliance for the HPLC system.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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

Deficiencies / Observations	Response of the Firm
i. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
ii. 2.3.S.3.1 a) The graphical representation submitted under characterization studies mentions "Escitalopram oxalate". Please clarify.	**Typographical Mistake**
iii. 2.3.R.2 In Analytical Procedures and Validation Information for Drug Product, Analytical Method for Testing of "Esomeprazole Capsule" has been submitted. Please justify.	**Typographical Mistake**
iv. 3.2.S.7.1 In Stability Summary and Conclusion, it has been mentioned that the drug substance is *"found stable under long term conditions temperature 25C + 2C and humidity 60 +5%) for a period of 3 years".* Please justify.	**Typographical Mistake**
v. Please provide stability results observed forthe Accelerated and Long-term studies of 03 stability batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for 06th Month Time Interval for each strength.	**Not submitted. 6th Month Stability Study Schedule Date is 31/12/2023.**
vi. 3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the Reference Standard.	COA of Working Standard against USP Ref. Lot. No. R043X0 has been submitted.
vii. Please provide Certificate of 21 CFR compliance for the HPLC system.	Copy of Certificate of Compliance for LabSolutions DB version 6, dated 26 March 2015 has been submitted.

	viii. Please provide evidence of Reference / Innovator's Packs used for Pharmaceutical Equivalence and CDP Studies for each strength.	Lyta 60mg Capsule, Batch No. 025C35	
	ix. Please provide Commitments / Undertakings as required in Sections 1.5.15 – 1.5.20. The submitted document is without signatures.	Submitted.	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake.**
- **Stability results observed for the Accelerated and Long-term studies of 03 stability batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for 06th Month Time Interval.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

548.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000945) issued w.e.f. 10-11-2021.
	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 3-1/2017-Lic dated 11th November, 2021 contains section approval for: - i. Tablet (Hormone) Section **ii. Tablet (General) Section.** iii. Capsule (General) Section. iv. Dry Powder Suspension (General) Section v. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23148 dated 20 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 15-09-2022 (Challan / Receipt # 9767511751)
	The proposed proprietary name / brand name	**PASTELO 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Escitalopram as oxalate (USP) … 10mg (USP Specifications)

	Pharmacotherapeutic Group of (API)	N06AB10, Selective serotonin reuptake inhibitors
	Pharmaceutical form of applied drug	White round film coated tablets
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRALEX 10mg Tablet by M/s Lundbeck Limited, MHRA Approved.
	For generic drugs (me-too status)	CIPRALEX 10mg Tablet by M/s Lundbeck Pakistan, Reg. No. 028467.
	Name and address of API manufacturer.	M/s Shodana Laboratories Private Limited Plot No. 24,25,26, Phase 1, Jeedimetla, Hyderabad-50055 Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against CIPRALEX 10mg Tablet by M/s Lundbeck Pakistan, Reg. No. 028467 by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against CIPRALEX 10mg Tablet by M/s Lundbeck Pakistan, Reg. No. 028467 in 03 dissolution media.

	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Shodana Laboratories Private Limited, India.		
API Lot No.	EO-092/21		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	11-2022	11-2022	11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter from M/s Legacy Pharmaceuticals, Peshawar regarding Loan of 100gms of API (Escitalopram Oxalate) has been submitted along with copy of Commercial Invoice No. EP/21-22/219 dated 16-08-2021 for Import of 10Kgs of Escitalopram Oxalate USP, Batch No. EO-092/21. **However, import approval from DRAP has not been submitted.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not provided.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not provided.**

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

Deficiencies / Observations	Response of the Firm

	i. Both the applied strengths i.e.PASTELO 10mg Tablets & PASTELO 20mg Tablets have the same description – *"White round film coated tablets"*. Please justify the same (with supporting evidence) as how to differentiate between the two strengths.	Firm has submitted that they will use a different color in future commercial production batches for differentiation between the two strengths.	
	ii. 2.3.S.4.1 API Specifications of the FPP manufacturer have been claimed as USP whereas in 2.3.S.4.5 Justification of the API Specifications, the same has been referred to Ph. Eur. Please justify.	**Typographical Mistake.** **API Specifications as per USP.**	
	iii. Information submitted in 2.3.S.7.3 a) Summary of the stability results observed for the accelerated and long-term studies does not match with the actual stability results provided in *Module 3* section 3.2.S.7.3. Please justify.	**Revised 2.3.S.7.3 a) Summary of the stability results.**	
	iv. 2.3.P.3.4 The Dissolution specifications have been mentioned as *NLT 85% in 30min*, whereas the same has been mentioned as *NLT 80% in 30min* and *NLT 80%*, on separate instances within the application dossier. Please justify.	**Typographical Mistake.**	
	v. Information provided in 2.3.P.8.3 (a) Conclusion of the stability studies does not match with the actual stability results provided in Module 3 section 3.2.P.8.3. Please justify.	**Revised 2.3.P.8.3 (a) Conclusion of the stability studies.**	
	vi. In 2.3.R.2 Analytical Procedures and Validation Information for Drug Product, it has been mentioned that *"the Method of Testing (Assay Method) is taken from BP 2017".* However, the Finished Product Specifications have been claimed as per USP. Please justify.	**Typographical Mistake.** **Finished Product Specifications have been claimed as per USP.**	
	vii. In Submitted Stability Study Data (Accelerated as well as Real Time) for Batch No. T-02, Significant Change (>5%) in Assay Results from its initial value has been observed at 6th Month Testing. Please justify.	**Typographical Mistake. Revised Assay Results of 0 Month Time Point to "101.97%".**	
	viii. 3.2.P.2.2.3 In submitted Comparative Dissolution Studies, dissolution results have been obtained >100% (up to 110%)	**The firm has submitted that they had used non calibrated volumetric**	

	on multiple instances, which is an indication that either there's a problem with the dissolution of the product or the uniformity of dosage units or both. Please justify with supporting evidences.	**cylinder having low tolerance thereby resulting in high test results.**	
	ix. API Lot No. is mentioned as "CPH2110109" in Stability Data Sheet. However, the same has neither been imported nor mentioned in any submitted supporting documents for Drug Substance. Please clarify.	**Typographical Mistake.** **API Lot No. is EO-092/21.**	
	x. Please provide approval of API/ DML of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted GMP Certificate was valid till 16/06/2022. Approval of API/ DML of API manufacturer issued by concerned regulatory authority of country of origin **has not been submitted.**	
	xi. Please provide approval of DRAP regarding Commercial Invoice No. EP/21-22/219 dated 16-08-2021 for Import of 10Kgs of Escitalopram Oxalate USP, Batch No. EO-092/21.	Submitted Certificate No. 10-88/2021-DRAP/3369 dated 02-09-2021 by AD I&E (Peshawar).	
	xii. Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	**Not Available**	
	xiii. Please provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	**Not Available**	

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake / Revision of Information.**
- **Scientific Rationale for obtaining dissolution results >100% (up to 110%) on multiple instances.**
- **Approval of API/ DML/ valid GMP of API manufacturer issued by concerned regulatory authority of country of origin.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

549.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000945) issued w.e.f. 10-11-2021.

	Evidence of approval of manufacturing facility	Copy of letter for Issuance of DML vide No. F. 3-1/2017-Lic dated 11th November, 2021 contains section approval for: - i. Tablet (Hormone) Section **ii. Tablet (General) Section.** iii. Capsule (General) Section. iv. Dry Powder Suspension (General) Section v. Cream / Ointment (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23149 dated 20 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 15-09-2022 (Challan / Receipt # 54642634458)
	The proposed proprietary name / brand name	**PASTELO 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Escitalopram as oxalate (USP) … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	N06AB10, Selective serotonin reuptake inhibitors
	Pharmaceutical form of applied drug	White round film coated tablets
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRALEX 20mg Tablet by M/s Lundbeck Limited, MHRA Approved.
	For generic drugs (me-too status)	CIPRALEX 20mg Tablet by M/s Lundbeck Pakistan, Reg. No. 059035.
	Name and address of API manufacturer.	M/s Shodana Laboratories Private Limited Plot No. 24,25,26, Phase 1, Jeedimetla, Hyderabad-50055 Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against CIPRALEX 20mg Tablet by M/s Lundbeck Pakistan, Reg. No. 059035 by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against CIPRALEX 20mg Tablet by M/s Lundbeck Pakistan, Reg. No. 059035 in 03 dissolution media.
	Analytical method validation/verification of product	Method verification studies have been submitted for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Shodana Laboratories Private Limited, India.		
API Lot No.	EO-092/21		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	11-2022	11-2022	11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Not provided.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter from M/s Legacy Pharmaceuticals, Peshawar regarding Loan of 100gms of API (Escitalopram Oxalate) has been submitted along with copy of Commercial Invoice No. EP/21-22/219 dated 16-08-2021 for Import of 10Kgs of Escitalopram Oxalate USP, Batch No. EO-092/21. **However, import approval from DRAP has not been submitted.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not provided.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not provided.**

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

Deficiencies / Observations	Response of the Firm
i. Both the applied strengths i.e. PASTELO 10mg Tablets & PASTELO 20mg Tablets have the same description – *"White round film coated tablets".* Please justify the same (with supporting evidence) as how to differentiate between the two strengths.	Firm has submitted that they will use a different color in future commercial production batches for differentiation between the two strengths.
ii. 2.3.S.4.1 API Specifications of the FPP manufacturer have been claimed as USP whereas in 2.3.S.4.5 Justification of the API Specifications, the same has been referred to Ph. Eur. Please justify.	**Typographical Mistake.** **API Specifications as per USP.**
iii. Information submitted in 2.3.S.7.3 a) Summary of the stability results observed for the accelerated and long-term studies does not match with the actual stability results provided in *Module 3* section 3.2.S.7.3. Please justify.	**Revised 2.3.S.7.3 a) Summary of the stability results.**
iv. 2.3.P.3.4 The Dissolution specifications have been mentioned as *NLT 85% in 30min*, whereas the same has been mentioned as *NLT 80% in*	**Typographical Mistake.**

30min and *NLT 80%*, on separate instances within the application dossier. Please justify.	**Revised 2.3.P.8.3 (a) Conclusion of the stability studies.**	
v. Information provided in 2.3.P.8.3 (a) Conclusion of the stability studies does not match with the actual stability results provided in Module 3 section 3.2.P.8.3. Please justify.	**Typographical Mistake.** **Finished Product Specifications have been claimed as per USP.**	
vi. In 2.3.R.2 Analytical Procedures and Validation Information for Drug Product, it has been mentioned that *"the Method of Testing (Assay Method) is taken from BP 2017".* However, the Finished Product Specifications have been claimed as per USP. Pleasejustify.	**Typographical Mistake. Revised Assay Results of 0 Month Time Point to "102.76%".**	
vii. In Submitted Stability Study Data (Accelerated as well as Real Time) for Batch No. T-05, Significant Change (>5%) in Assay Results from its initial value has been observed at 6th Month Testing. Please justify.	**Typographical Mistake. Revised Assay Results of 0 Month Time Point to "101.49%".**	
viii. In Submitted Stability Study Data (Real Time) for Batch No. T-06, Significant Change (>5%) in Assay Results from its initial value has been observed at 6th Month Testing. Please justify.	**The firm has submitted that they had used non calibrated volumetric cylinder having low tolerance thereby resulting in high test results.**	
ix. 3.2.P.2.2.3 In submitted Comparative Dissolution Studies, dissolution results have been obtained >100% (up to 110%) on multiple instances, which is an indication that either there's a problem with the dissolution of the product or the uniformity of dosage units or both. Please justify with supporting evidences.	**Typographical Mistake.** **API Lot No. is EO-092/21.**	
x. API Lot No. is mentioned as "CPH2110109" in Stability DataSheet. However, the same has neither been imported nor mentioned in any submitted supporting documents for Drug Substance. Please clarify.	Submitted GMP Certificate was validtill 16/06/2022. Approval of API/ DMLof API manufacturer issued by concerned regulatory authority of country of origin **has not been submitted.** Submitted Certificate No. 10-88/2021-DRAP/3369 dated 02-09-2021 by AD I&E (Peshawar).	

xi.	Please provide approval of API/ DML of API manufacturer issued by concerned regulatory authority of country of origin.	**Not Available**	
xii.	Please provide approval of DRAP regarding Commercial Invoice No. EP/21-22/219 dated 16-08-2021 for Import of 10Kgs of Escitalopram Oxalate USP, Batch No. EO-092/21.	**Not Available**	
xiii.	Please provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.		
xiv.	Please provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).		

Decision: Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction for each Typographical Mistake / Revision of Information.**
- **Scientific Rationale for obtaining dissolution results >100% (up to 110%) on multiple instances.**
- **Approval of API/ DML/ valid GMP of API manufacturer issued by concerned regulatory authority of country of origin.**

Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

Agenda of Evaluator PEC-IV

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

a. New DML

M/s Medevo (Private) Ltd. . **(New DML)**
CLB in its 288th meeting held on 18th October 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following Two (02) sections to M/s Medevo (Private) Ltd.

1) Eye Drops (General)
2) Eye Ointment (General)

Eye Drops (General)		
550.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23152 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 10783694194
	The proposed proprietary name / brand name	Surgilot Eye Drops (0.5% Ophthalmic Suspension)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Loteprednol Etabonate……5mg
	Pharmaceutical form of applied drug	Milky white Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Steroid
	Reference to Finished product specifications	Manufacturer specs
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LOTEMAX ophthalmic suspension/drops; of USFDA Approved
	For generic drugs (me-too status)	Lotepred forte Ophthalmic suspension of M/s of Sante private limited Reg# 0674458
	Name and address of API manufacturer.	M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Lotepred Forte of M/s Sante Pharmaceuticals by performing quality tests Identification, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA			
Manufacturer of API	Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.		
API Lot No.	LOT/MS/22/009		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LOTF-Trial001	LOTF-Trial002	LOTF-Trial003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	03-12-2022	03-12-2022	03-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6111950) issued by Food and Drugs Administration Maharashtra state, dated 14-03-2023 and valid till 13-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Drugs import License # K-987059032758, dated; 29-09-2022 specifying Loteprednol Etabonate.(Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

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

Evaluation by PEC:

S.No	Section	Shortcoming
1.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
2.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.
4.	3.2.S.4.4	COA of drug substance by drug product mentioned BP specification complies while drug substance is not available in BP Pharmacopeia.
5.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
7.	3.2.P.3.5	Composition in 3.2.P.1 and process validation is different. Clarify.
8.	3.2.P.5.1	• Specification mentioned are USP. While it is not available in USP Pharmacopeia • Innovator product pH range is 5.3 – 5.6 while your pH is 5.5 – 7.0. Clarify.
9.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
10.	3.2.P.5.4	The copies of complete analysis of at least two batches shall be provided.
11.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submitted raw data and analytical testing method of assay does not match with each other. • Raw data of stability studies submitted only of 6th month. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing

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

551.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23156 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 929420703
	The proposed proprietary name / brand name	Surgilot-T 0.5/0.3% Opthalmic Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Loteprednol Etabonate……5mg Tobramycin……3mg
	Pharmaceutical form of applied drug	Milky white Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Steroid and antibiotic
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZYLET ophthalmic suspension/drops; of USFDA Approved
	For generic drugs (me-too status)	Lotepred-T Ophthalmic suspension of M/s of Sante private limited Reg# 070515
	Name and address of API manufacturer.	**Loteprednol Etabonate:** M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India. **Tobramycin:** Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Loteprednol Etabonate**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Tobramycin:** Firm has submitted stability study data of 3 batches of drug substance at both

		accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Lotepred-T of M/s Sante Pharmaceuticals by performing quality tests Identification, Clarity, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	**Loteprednol Etabonate**: Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India. **Tobramycin:** Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.		
API Lot No.	**Loteprednol Etabonate:**LOT/MS/22/009 **Tobramycin:** 08210702-U		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LOTT-Trial001	LOTT-Trial002	LOTT-Trial003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	14-12-2022	14-12-2022	14-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Loteprednol Etabonate:** Firm has submitted copy of GMP certificate (No. 6111950) issued by Food and Drugs Administration Maharashtra state, dated 14-03-2023 and valid till 13-03-2024 **Tobramycin:** Firm has submitted copy of GMP certificate (No. HE2021010F) issued by NMPA, dated 30-11-2019 and valid till 29-11-2024

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Loteprednol Etabonate:** An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Drugs import License # K-987059032758, dated; 29-09-2022 specifying Loteprednol Etabonate.(Innovotek pharmaceuticals) **Tobramycin:**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.5.5	Complete Pharmacological group is not mentioned
2.	1.6.5	Submitted GMP certificate for drug substance (Tobramycin) could not be verified from NMPA site. Clarify.
3.	3.2.S.4.1	Copies of the Drug substance (Loteprednol Etabonate) specifications by Drug Product manufacturer is required.
4.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Loteprednol Etabonate) by Drug Product manufacturer is required.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) (Loteprednol Etabonate & Tobramycin)shall be submitted.
6.	3.2.S.4.4	• As per USP monograph for Ophthalmic dosage form Tobramycin must be sterile but COA of drug substance manufacturer and drug product manufacturer it is not evident that it is sterile. • COA of drug substance by drug product manufacturer specifies result of assay in percentage (%) while USP monograph specifies NLT 900 µg/mg of tobramycin on the anhydrous basis. Clarify • COA of drug substance (Loteprednol Etabonate) by drug product mentioned BP specification complies, while drug substance is not available in BP Pharmacopeia.
7.	3.2.S.7	Submit stability studies of drug substance (Tobramycin) as per zone IV-A/B
8.	3.2.P.1	Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
9.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
10.	3.2.P.5.1	Innovator product pH range is 5.5 – 6.2 while your pH is 5.5 – 6.5. Clarify.
11.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
12.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submitted raw data and analytical testing method of assay of both Loteprednol Etabonate & Tobramycin does not match with each other. • Raw data of stability studies submitted only of 6th month. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

		• Documents for the procurement of API with approval from DRAP (Tobramycin)	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.			
552.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.	
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore	
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	GMP status of the firm	New DML issued dated: 08-11-2022	
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales	
	Dy. No. and date of submission	Dy No. 26021 dated 27-10-2023	
	Details of fee submitted	Rs.30,000/- Deposit slip # 31222688015	
	The proposed proprietary name / brand name	Surgitob 0.3% Eye Drops	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Tobramycin …….3mg	
	Pharmaceutical form of applied drug	Milky white Ophthalmic Suspension	
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotic	
	Reference to Finished product specifications	USP	
	Proposed Pack size	5ml	
	Proposed unit price	As per SRO	
	The status in reference regulatory authorities	TOBREX (Ophthalmic solution/drops) of USFDA Approved)	
	For generic drugs (me-too status)	Tobrex Eye Drop manufactured by Novartis. Reg#097352	
	Name and address of API manufacturer.	M/s Chongqing Daxin Pharmaceuticals Co.Ltd. BeiBei, ChongQing people Republic of China.	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.	
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general	

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Tobrex Eye Drops manufactured by Alcon by performing quality tests Identification, Description/Appearance, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.		
API Lot No.	08191203-U		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TMD-Trial001	TMD -Trial002	TMD -Trial003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	30-11-2022	30-11-2022	30-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No inspection of Next Pharmaceuticals have been conducted on the basis of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE2021010F) issued by NMPA, dated 30-11-2019 and valid till 29-11-2024

3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # specifying Invoice #PHL206738, dated; 10-03-2020 specifyingTobramycin base Batch #.08191203-U (Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Submitted GMP certificate for drug substance could not be verified from NMPA site. Clarify.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.
5.	3.2.S.4.4	As per USP monograph for Ophthalmic dosage form Tobramycin must be sterile but from COA of drug substance manufacturer and drug product manufacturer it is not evident that it is sterile. COA of drug substance by drug product manufacturer specifies result of assay in percentage (%) while USP monograph specifies NLT 900 µg/mg of tobramycin on the anhydrous basis. Clarify
6.	3.2.S.7	Submit stability studies of drug substance as per zone IV-A/B
7.	3.2.P.1	Innovator product add Sulfuric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
8.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
9.	3.2.P.5.2	Detailed analytical procedures used for testing the drug product shall be provided.
10.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
11.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Concentration of standard and sample in raw data of stability is changed from USP monograph. • Initial testing raw data of 3 batches not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

553.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore

	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23155 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 9658797258
	The proposed proprietary name / brand name	**Surgimox Eye Drop (0.5% ophthalmic Solution)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Moxifloxacin Hcl eq. to Moxifloxacin…….5mg
	Pharmaceutical form of applied drug	Antibiotic
	Pharmacotherapeutic Group of (API)	Clear yellowish solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VIGAMOX (USFDA Approved)
	For generic drugs (me-too status)	Vigamox Eye Drop of by Novartis Pharma Reg # 093920.
	Name and address of API manufacturer.	M/s Zheijiang Guobang Pharmaceuticals Co., Ltd. No. 6 Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for 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 **2** batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Vigamox Eye Drop manufactured by Alcon Laboratories. by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	M/s Zheijiang Guobang Pharmaceuticals Co., Ltd. No. 6 Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.		
API Lot No.	E109-220312-1		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MOXE Trial 001	MOXE Trial 002	MOXE Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	23-11-2022	23-11-2022	23-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Biorex pharmaceuticals submitted. Firm has submitted copy of Form 5 (Drug Import License, dated; 11-08-2020 specifying Moxifloxacin HCL (Biorex pharmaceuticals) Firm has submitted copy of Clearance certificate # specifying Invoice #GBP2022-0973, dated; 21-07-2020 specifying Moxifloxacin HCL Batch #.

		E109-220312-1 issued on 31-08-2022(Biorex pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.1	Copies of the Drug substance specifications by both Drug substance & Drug Product manufacturer is required.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.
5.	3.2.S.7	Submit Accelerated and long term stability studies of drug substance for 3 batches
6.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
7.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
8.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.
10.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submitted raw data does not match with analytical testing method of assay and USP monograph. Clarify. • Initial testing raw data of 3 batches not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit clearance certificate in readable form.

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

554.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022

	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23154 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 087533119
	The proposed proprietary name / brand name	**Surgipad DS Eye Drop (0.2% Ophthalmic Solution)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Olopatadine Hcl eq. to Olopatadine…….2mg
	Pharmaceutical form of applied drug	Antiallergics
	Pharmacotherapeutic Group of (API)	Ophthalmic Clear solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PATADAY (USFDA Approved)
	For generic drugs (me-too status)	Olotek-DS Eye Drop manufactured by Innovotek Pharmaceuticals.
	Name and address of API manufacturer.	M/s Precise chemipharma private limited India. Address: C-384 TTC Industrial Area MiDC, Pawane Village, Navi Mumbai, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 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	Pharmaceutical Equivalence have been established against the Olotek-DS Eye Drop manufactured by Innovotek Pharmaceuticals. by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	M/s Precise chemipharma private limited India. Address: C-384 TTC Industrial Area MiDC, Pawane Village, Navi Mumbai, India.		
API Lot No.	055008062020		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OLP Trial 001	OLP Trial 002	OLP Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	25-11-2022	25-11-2022	25-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6109110) issued by Food & Adminstration Maharashtra state India, (for Precise Biopharma Pvt Ltd) dated 19-09-2022 and valid till 15-09-2023 (Firm submitted Decleration from drug substance manufacturer that their company name change from Precise chemipharm Pvt Ltd to Precise Biopharma pvt Ltd.)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of form 5 and Clearance certificate specifying Invoice #EXPI/00055/20-21, dated; 08-07-2020 specifying Olopatadine Hcl Batch #.055008062020 (Innovotek pharmaceuticals)

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

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.
3.	3.2.P.1	Innovator product add Hydrochloric acid/ or Sodium hydroxide to adjust pH while in your formulation these are not included than how pH is adjusted.
4.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
5.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
6.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.
7.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submitted raw data does not match with analytical testing method of assay and USP monograph. Clarify. • Initial testing raw data of 3 batches not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit clearance certificate in readable form.

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

555.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23153 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 087952225
	The proposed proprietary name / brand name	**Surgitor-T Eye Drop**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dorzolamide Hcl eq. to Dorzolamide…….20mg Timolol Maleate eq. to Timolol …….5mg
	Pharmaceutical form of applied drug	Anti-glaucoma
	Pharmacotherapeutic Group of (API)	Ophthalmic Clear solution
	Reference to Finished product specifications	USP
	Proposed Pack size	5 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COSOPT (USFDA Approved)
	For generic drugs (me-too status)	Cosopt Eye Drop manufactured by OBS Pakistan Reg# 025294
	Name and address of API manufacturer.	**Dorzolamide Hcl & Timolol Maleate**:M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for 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)	**Dorzolamide Hcl:** Firm has submitted stability study data of 2 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Timolol Maleate:** Firm has submitted stability study data of 2 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Cosopt Eye Drop manufactured by SANTEN Pharmaceuticals Co, Ltd.. by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	**Dorzolamide Hcl & Timolol Maleate:**M/s Flax Laboratories B-29/1, MIDC Mahad, birvadi village, Dist, raigad, Maharashtra, India.		
API Lot No.	**Dorzolamide Hcl:** DOR/21/002 **Timolol Maleate:** TIM/21/001		
Description of Pack (Container closure system)	LDPE bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DRTI Trial 001	DRTI Trial 002	DRTI Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	27-11-2022	27-11-2022	27-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dorzolamide Hcl & Timolol Maleate:**Firm has submitted copy of GMP certificate (No. 6111950) issued by Food and Drugs Administration Maharashtra state, dated 14-03-2023 and valid till 13-03-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between Medevo (Pvt) Limited and Innovotek pharmaceuticals submitted. Firm has submitted copy of form 5 and Clearance certificate specifying Invoice #FLX/EX/00055/20-21/036, dated; 15-03-2021 specifying Dorzolamide Hcl Batch #. DOR/21/002 & Timolol Maleate Batch # TIM/21/001 (Innovotek pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

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

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.1	Copies of the Drug substance (Dorzolamide Hcl & Timolol Maleate)specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Dorzolamide Hcl & Timolol Maleate)Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) Dorzolamide Hcl & Timolol Maleate shall be submitted.
5.	3.2.S.7	Submit Accelerated and long term stability studies of drug substance (Dorzolamide Hcl & Timolol Maleate) for 3 batches.
6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
7.	3.2.P.5.2	Standard and sample concentrations of Dorzolamide Hcl are different from USP monograph
8.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.
10.	3.2.P.8	• Stability studies are conducted at Real time : 30˚C ± 2˚C / 65% ± 5%RH and Accelerated: 40˚C ± 2˚C / 75% ± 5%RH but water loss test calculation is not done as per ICH guidelines. • Water loss test submitted for only 3 months. Clarify. • Submitted raw data of Timolol Maleate does not match with analytical testing method of assay and USP monograph. Clarify. • Initial testing raw data of 3 batches not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit clearance certificate in readable form.

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

Eye Ointment (General)

556.	Name, address of Applicant / Marketing Authorization Holder	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore.
	Name, address of Manufacturing site.	M/s Medevo (Private) Ltd. Plot No # 94 sundar industrial Estate Raiwind Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued dated: 08-11-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of DML letter dated 08-11-2022 specifying EYE Drops (General) Section

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 26021 dated 22-08-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 79054979901
	The proposed proprietary name / brand name	Surgitob 0.3% Eye Ointment
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Tobramycin …….3mg
	Pharmaceutical form of applied drug	Off White semi solid ointment
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	3.5gm
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TOBREX (Ophthalmic ophthalmic ointment) of USFDA Approved)
	For generic drugs (me-too status)	Tobrex Eye Drop manufactured by Novartis. Reg#093921
	Name and address of API manufacturer.	M/s Chongqing Daxin Pharmaceuticals Co.Ltd. BeiBei, ChongQing people Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25°C ± 2°C / 60 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Tobrex Ointment manufactured by M/s Novartis Private Ltd. by performing quality tests Identification, Description/Appearance, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Chongqing Daxin Pharmaceuticals Co.Ltd. BEiBei, ChongQing people Republic of China.		
API Lot No.	08210702-U		
Description of Pack (Container closure system)	Collapsible Aluminium Tubes		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TME Trial 001	TME Trial 002	TME Trial 003
Batch Size	5L (1000 Packs)	5L (1000 Packs)	5L (1000 Packs)
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	14-12-2022	30-11-2022	14-12-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No inspection of Next Pharmaceuticals have been conducted on the basis of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE2021010F) issued by NMPA, dated 30-11-2019 and valid till 29-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Submitted GMP certificate for drug substance could not be verified from NMPA site. Clarify.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer both drug substance(s) shall be submitted.

3.	3.2.S.4.4	As per USP monograph for Ophthalmic dosage form Tobramycin must be sterile but from COA of drug substance manufacturer and drug product manufacturer it is not evident that it is sterile. COA of drug substance by drug product manufacturer specifies result of assay in percentage (%) while USP monograph specifies NLT 900 µg/mg of tobramycin on the anhydrous basis. Clarify	
4.	3.2.S.7	Submit stability studies of drug substance as per zone IV-A/B	
5.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	
6.	3.2.P.5.3	Analytical method validation protocol and report for drug product shall be performed.	
7.	3.2.P.8	• Submitted raw data and analytical testing method of assay does not match with each other. • Initial testing raw data of 3 batches not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Documents for the procurement of API with approval from DRAP	

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

M/s DS Pharma. **(New DML)**
CLB in its 289th meeting held on 23rd January 2023 has considered and approved the grant of Drug Manufacturing License by way of formulation with following Two (02) sections to M/s DS Pharma.

1) Liquid Injectable (SVP) (Ampoule) Section (General)
2) Liquid Injectable (SVP) (Ampoule) Section (Steroid)

557.	Name, address of Applicant / Marketing Authorization Holder	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Name, address of Manufacturing site.	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 22-02-2023 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 15826 dated 22-06-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 8406233477
	The proposed proprietary name / brand name	Aqua-DS Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml ampoule contains: Sterile water for injection .....5ml (USP Specification)
	Pharmaceutical form of applied drug	solvent
	Pharmacotherapeutic Group of (API)	Clear colourless odourless liquid solution filled in Clear glass ampoule 5ml USP type 1
	Reference to Finished product specifications	USP

	Proposed Pack size	5mlx5's, 5mlx25's, 5mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sterile Water for injection 5ml by MEDEFIL INC., USFDA Approved.
	For generic drugs (me-too status)	Sterile Water for Injection 5ml of M/s Islam Pharmaceuticals, (Reg. No. 113070)
	Name and address of API manufacturer.	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	NA
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product WFI injection manufactured by GSK Pharma
	Analytical method validation/verification of product	NA

STABILITY STUDY DATA

Manufacturer of API	M/s **DS Pharma** Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
API Lot No.	
Description of Pack (Container closure system)	5ml x 100's Ampoules Clear glass ampoule USP type 1
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	WT-001	WT-002	WT-003
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No inspection of Next Pharmaceuticals have been conducted on the basis of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	NA
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	REPLY
1.	3.2.S.4.4	• Submit COA of bulk water as per USP monograph. • Submit 6th month stability studies data.	• COA of bulk water for one batch submitted in which Batch size is 2.5 litres • 6th month stability studies data submitted.

Decision: Approved with USP specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of COAs of bulk water used for manufacturing of drug product stability batches.**

558.	Name, address of Applicant / Marketing Authorization Holder	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Name, address of Manufacturing site.	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 22-02-2023 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 16134 dated 26-06-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 45409436284
	The proposed proprietary name / brand name	**Gentadis 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Gentamicin as Sulphate..... 80 mg (USP Specification)
	Pharmaceutical form of applied drug	Amino glycosides Antibiotics
	Pharmacotherapeutic Group of (API)	Clear, colourless transparent solution filled in Clear glass ampoule USP type 1
	Reference to Finished product specifications	USP
	Proposed Pack size	2mlx5's, 2mlx10's, 2mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Gentamicin 40mg/ml Injection (2ml) of MHRA Approved
	For generic drugs (me-too status)	Genticyn injection 80mg/2ml of M/s Ray pharma, (Reg. No. 000500)
	Name and address of API manufacturer.	Fuan pharmaceutical group Yantai Justaware Pharmaceutical Co,. Limited No.1 Yanfu Road, Zhifu District, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Genticyn injection manufactured by Ray pharma by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Fuan pharmaceutical group Yantai Justaware Pharmaceutical Co,. Limited No.1 Yanfu Road, Zhifu District, Shandong Province, China		
API Lot No.	201909005		
Description of Pack (Container closure system)	2ml x 100's Ampoules		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	GT-001	GT-002	GT-003
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	19-03-2023	19-03-2023	19-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. SD20190963) dated 17-07-2019 issued by China Food and Drug Administration. The certificate is valid till 16-07-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between M/s DS pharma and M/s NS pharma submitted. Firm has submitted copy of form 5 and Commercial Invoice #VET19100802, dated; 08-10-2019 cleared by DRAP (Lahore) dated: 16-10-2019 specifying. Gentamicin sulphate Batch # 201909005 (M/s NS pharma)

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

Evaluation by PEC:

S.No	Section	Shortcoming
1.	3.2.S.4.2	• Provide standard and sample preparation in detail instead of mentioning suitable quantity. • USP Microbial assay specify 5 standard concentration (S_{1-} $S_{5)}$ while you are using 3 standard concentrations. Clarify.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) in accordance to USP microbial assay shall be submitted.
3.	3.2.P.1	• Propylene Glycol is not used by reference product while you are using . Justify. • In reference product Sulphuric acid (2.5N) & Sodium hydroxide are used for pH adjustment while in your product these are not added than pH adjustment is done.
4.	3.2.P.5.1	Innovator specifications are mentioned while in section 1.5.6 USP specifications are applied. Clarify.
5.	3.2.P.5.2	• Provide standard and sample preparation in detail instead of mentioning suitable quantity. • USP Microbial assay specify 5 standard concentration (S_{1-} $S_{5)}$ while you are using 3 standard concentrations. Clarify. • Calculations details for microbial assay not submitted.
6.	3.2.P.5.3	Assay is performed by microbial assay while analytical method verification submitted by HPLC method. Justify.
7.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided
8.	3.2.P.7	Submit details of primary Container Closure System.
9.	3.2.P.8	• Raw data for microbial Assay not submitted. • Submit 6th month stability studies data.

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

559.	Name, address of Applicant / Marketing Authorization Holder	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Name, address of Manufacturing site.	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 22-02-2023 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 16140 dated 26-06-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 079958644
	The proposed proprietary name / brand name	**Licaine 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Lidocaine HCl..... 40 mg (USP Specification)
	Pharmaceutical form of applied drug	Anesthetic (Local), Antiarrhythmic (Class IB)
	Pharmacotherapeutic Group of (API)	Clear, colourless transparent solution filled in 2ml Clear glass ampoule USP type 1
	Reference to Finished product specifications	USP
	Proposed Pack size	2mlx5's, 2mlx10's, 2mlx25's, 2mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lidocaine 2% w/v solution for injection by Hameln pharma ltd, of MHRA approved
	For generic drugs (me-too status)	Xylex 2% Injection of M/s Venus pharma, (Reg. No. 012958)
	Name and address of API manufacturer.	M/s Gufic Biosciences Limited. N,H. No. 8 Near Grid, At & PO kabilpore-396 424 Navsari India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Surgicain injection manufactured by Harmann Pharmaceutical Laboratories Pvt. Ltd by performing quality tests Identification, Description/Appearance, pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Gufic Biosciences Limited. N,H. No. 8 Near Grid, At &PO kabilpore-396 424 Navsari India		
API Lot No.	API/LIH/202161		
Description of Pack (Container closure system)	2ml x 100's Ampoules		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LT-001	LT-002	LT-003
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	21-03-2023	21-03-2023	21-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.20081523) dated 07-08-2020 issued by Food and Drugs Control Administration Gujrat State India. The certificate is valid till 06-08-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	An agreement of API's Loan between M/s DS pharma and M/s NS pharma submitted. Firm has submitted copy of form 5 and Commercial Invoice #NBEXBD2021000224, dated; 10-12-2020 cleared by DRAP (Lahore) dated: 19-01-2021 specifying. Lidocaine HCL Batch # API/LIH/202161 (M/s NS pharma)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted the audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of GMP Certificate (No.22093515) dated 05-09-2022 issued by Food and Drugs Control Administration Gujrat State India. The certificate is valid till 04-09-2025
2.	2.3.R.1.1	• Overage is used in stability batches. Reference product specify Each 1 ml contains 20.0 mg of lidocaine hydrochloride, corresponding to 16.2 mg lidocaine while your product contains Each ml contains 21.28mg. Clarify. • How pH is adjusted without Hydrochloric Acid & Sodium Hydroxide.	• As our label claim is Lidocain as HCl and the factor of lidocaine hydrochloride is 1.064. So by applying factor (20 × 1.064 = 21.28 mg) . here potency of HCl salt is adjusted. ***(As per reference product 20mg lidocaine Hydrochloride* corresponding to 16.2 mg lidocaine. Lidocaine as HCl is not available in RRA.)** • The pH of the injection is adjusted with 1M HCl or 1M NaOH when necessary. Revised formulation mentioning this is attached.
3.	3.2.S.4.3	• In analytical Method Verification studies in accuracy and precision what concentrations is used. • In analytical Method Verification studies specificity of drug substance which Placebo is used.	• Revised method verification is attached. • Placebo term here represent diluent/medium in specificity ofdrug substance method verification.
4.	3.2.S.4.4	Drug substance manufacturer applied on BP monograph while you have mentioned on USP monograph.	We have applied USP method for drug substance and also verified it and submitted its record.
5.	3.2.P.1	In reference product Hydrochloric Acid & Sodium Hydroxide are used for pH adjustment while in your product these are not added than how pH adjustment is done.	The pH of the injection is adjusted with 1M HCl or 1M NaOH when necessary. Revised formulation mentioning this is attached.
6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	No preservative is used in the formulation so preservative effectiveness studies is not applicable. effectiveness study
7.	3.2.P.5.1	Bacterial Endotoxin test and particulate matters are not part of specification as specified in USP monograph. Clarify.	We have performed Bacterial endotoxin and particulate matter test. Revisedspecifications is attached.
8.	3.2.P.5.3	Analytical Method Verification Studies Concentrations are not as per USP monograph concentrations.	Revised method Verification documents are attached.
9.	3.2.P.7	Submit details of primary Container Closure System.	Filled in 2cc amber colored Type-1 glass.
10.	3.2.P.8	• Sterility test and Bacterial Endotoxin test are not part of stability studies. • Submit complete Raw data for stability studies. • Submit 6th month stability studies data.	• We have performed sterility test and bacterial endotoxin test during stability studies. • **Raw data for stability studies is not submitted.** • 6th month stability studies data submitted
Decision: Registration Board deferred the case for following:			

• **Revision of label claim as per reference product along with submission of fee of Rs:30000/- for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021** • **Submission of complete Raw data for stability studies of 03 batches.**		
560.	Name, address of Applicant / Marketing Authorization Holder	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Name, address of Manufacturing site.	M/s DS Pharma Plot No.13, Sher Shah Industrial Estate Qila Sattar Shah, Sheikhupura
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 22-02-2023 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 16135 dated 26-06-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 3711866112
	The proposed proprietary name / brand name	**Ds-B12 Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Cyanocobalamin… .....1000 mcg (USP Specification)
	Pharmaceutical form of applied drug	Corrinoids (Vitamin b12)
	Pharmacotherapeutic Group of (API)	Clear, red colour solution filled in amber coloured glass ampoule
	Reference to Finished product specifications	
	Proposed Pack size	2mlx5's, 2mlx25's, 2mlx100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	B12 Steigerwald solution for injection by Bayer Vital GmbH (**Germany** Approved)
	For generic drugs (me-too status)	Vitamin B-12 1000mcg/2ml Injection of M/s Avensis Pharmaceuticals(Reg. No. 012091)
	Name and address of API manufacturer.	Hebei Yuxing Bio-Engineering Co. Ltd Address: Xicheng District, Ningjin country, Xing Tai city, Hebei Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product B12 injection manufactured by Venus pharma.by performing quality tests Identification, , pH, Assay, and Sterility Test,).
	Analytical method validation/verification of product	

STABILITY STUDY DATA			
Manufacturer of API	Hebei Yuxing Bio-Engineering Co. Ltd Address: Xicheng District, Ningjin country, Xing Tai city, Hebei Province, China		
API Lot No.	C200504F		
Description of Pack (Container closure system)	2ml x 25's Ampoules		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	BT-001	BT-002	BT-003
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	17-03-2023	17-03-2023	17-03-2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. HE20190142) dated 30-11-2019 issued by China Food and Drug Administration. The certificate is valid till 29-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Testing is done by UV method
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.5.5	Submit Correct pharmacological group with submission of requisite fee.	Correction of pharmacological group without submission of fee as follows: Supplement for Vitamin B12 Deficiency
2.	1.5.6	No specification are claimed in this section.	Our product specifications are USP. Revised document is attached.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted in accordance to USP monograph.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) submitted as per USP monograph.
4.	3.2.S.P.1	• Benzyl Alcohol and Sodium dihydrogen phosphate are not used by reference product while used in your formulation. Clarify or submit compatibility studies. • Hydrochloric acid 8.5% is used by reference product while it is not in you product. Clarify.	• Our product is stable in this formulation and also performed compatibility studies and report is attached. • We adjusted pH with HCl 8.5% when necessary.
5.	3.2.P.5.1	Bacterial Endotoxin test is not part of specification as specified in USP monograph. Clarify.	Revised specifications with Bacterial Endotoxin submitted.
6.	3.2.P.5.3	Analytical Method Verification studies Concentrations are not as per USP monograph concentrations. Clarify.	Revised analytical method Verification studies as per USP monograph submitted.
7.	3.2.P.7	Submit details of primary Container Closure System.	Filled in 2cc amber coloured Type-1 glass.
8.	3.2.P.8	• Submit Import documents in clear form.. • Submit complete Raw data for stability studies . • Submit 6th month stability studies data.	• An agreement of API's Loan between M/s DS pharma and M/s NS pharma submitted. Firm has submitted copy of Commercial Invoice #20KLM-0727A, dated; 27-07-2020 cleared by DRAP (Lahore) dated: 29-10-2020

			specifying. Cyanocobalamin Batch # C200504F (M/s NS pharma). • **Raw data for stability studies submitted.** • 6th month stability studies data submitted.	

Decision: Registration Board Deferred the case for submission of complete Raw data for stability studies of 03 batches.

M/s Fleming Pharmaceutical. (New DML)
CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five (05) sections to M/s M/s Fleming Pharmaceutical.
1. Oral Dry Powder for suspension(Penicillin)
2. Capsule (Penicillin)
3. Tablet (Penicillin)
4. Dry Powder Injectable (Penicillin)
5. Dry Powder Injectable (Carbapenem)

Dry Powder Injectable (Carbapenem)

561.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying Dry powder injectable(Carbapenem) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 25740 dated 24-10-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 217358766635
	The proposed proprietary name / brand name	**Flemaxin 250 mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem Monohydrate eq to Imipenem…… 250 mg Cilastatin Sodium eq to Cilastatin…..250 mg
	Pharmaceutical form of applied drug	Carbapenem antibiotics
	Pharmacotherapeutic Group of (API)	A white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection (USFDA Approved)

	For generic drugs (me-too status)	Cilapen 250 mg Injection of M/s Bosh pharmaceuticals Reg # 048490
	Name and address of API manufacturer.	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Cilapen 250 mg Injection manufactured by Bosch pharmaceuticals (PVT) LTD by performing quality tests Description, pH, Bacterial Endotoxins, Particulate matters, Assay, and Sterility Test, Loss on drying.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.
API Lot No.	0069E1
Description of Pack (Container closure system)	FPP is packed in a white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	1190 Vials	1190 Vials	1190 Vials
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	21-05-2022	21-05-2022	21-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Take API's Loan from M/s Stallion Pharmaceuticals Firm has submitted copy of Clearnce certificate # E-417242824518, dated; 17-03-2020 issued by DRAP (Lahore) specifying Invoice # 100809 dated: 10-03-2022 specifying. Imipenem and Cilastatin Sodium Batch # 0069E1 (M/s Stallion Pharmaceuticals.)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug substance manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.
4.	3.2.S.5 & 3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
5.	3.2.P.6	COA of reference standard submitted for Cilastatin Sodium while USP monograph specified Cilastatin Ammonium as reference standard.

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

562.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying Dry powder injectable(Carbapenem) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 25741 dated 24-10-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 68456344007
	The proposed proprietary name / brand name	**Flemaxin 500 mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem Monohydrate eq to Imipenem…… 500 mg Cilastatin Sodium eq to Cilastatin….....500 mg
	Pharmaceutical form of applied drug	Carbapenem antibiotics
	Pharmacotherapeutic Group of (API)	A white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection (USFDA Approved)
	For generic drugs (me-too status)	Cilapen 500 mg Injection of M/s Bosh pharmaceuticals Reg # 048491
	Name and address of API manufacturer.	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Cilapen 500 mg Injection manufactured by Bosch pharmaceuticals (PVT) LTD by performing quality tests Description, pH, Bacterial Endotoxins, Particulate matters, Assay, and Sterility Test, Loss on drying.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.		
API Lot No.	0069E1		
Description of Pack (Container closure system)	FPP is packed in a white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	1190 Vials	1190 Vials	1190 Vials
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	21-05-2022	21-05-2022	21-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Take API's Loan from M/s Stallion Pharmaceuticals Firm has submitted copy of Clearnce certificate # E-417242824518, dated; 17-03-2020 issued by DRAP (Lahore) specifying Invoice # 100809 dated: 10-03-2022 specifying. Imipenem and Cilastatin Sodium Batch # 0069E1 (M/s Stallion Pharmaceuticals.)

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

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug substance manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.
4.	3.2.S.5 & 3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
5.	3.2.P.6	COA of reference standard submitted for Cilastatin Sodium while USP monograph specified Cilastatin Ammonium as reference standard.

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

563.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying Dry powder injectable(Carbapenem) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 20847 dated 28-08-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 477158197
	The proposed proprietary name / brand name	**Flerta 1.0 g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ertapenem sodium eq to Ertapenem 1.0g
	Pharmaceutical form of applied drug	Carbapenem antibiotics
	Pharmacotherapeutic Group of (API)	White to light yellow lyophilized powder.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Invanz 1.0 g Injection (USFDA Approved)
	For generic drugs (me-too status)	Ernem 1.0 g Injection of Genix Pharma.Reg # 081179
	Name and address of API manufacturer.	Savior lifetec corporation. TINAN SITE Block A/B, 11 DA-SHUEN 9TH ROAD, XINSHI DISTRICT. TAINAN CITY, TW-74145, TAIWAN.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Invanz 1.0 g injection manufactured by Merck sharp & Dohme chibret (Mirabel), France by performing quality tests Description, pH, Bacterial Endotoxins, Particulate matters, Assay, and Sterility Test, Loss on drying.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.
API Lot No.	805028AA011
Description of Pack	FPP is packed in a white or light yellow powder filled in glass vial properly

(Container closure system)	sealed and labelled and packed in white colored unit cardboard box.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	333 Vials	333 Vials	333 Vials
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	12-10-2022	12-10-2022	12-10-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Commercial invoice # s220721-002, dated; 21-07-2022 specifying. Ertapenem Sodium Batch # 805028AA011
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	2.3.A.1	Provide evidence of Atomic absorption spectrometer.
3.	3.2.S.4.4	Specification for assay by drug substance manufacturer is 77.0% -82.7% while in COA of drug substance specifications for assay are 77.0% -85%
4.	3.2.S.5	Submitted drug substance analytical procedure mandates use of Ertapenem Sodium as working standard whereas submitted COA is of Ertapenem sodium lyophilized powder for injection. justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium.
5.	3.2.S.7	Justification shall be submitted for conducting drug substance stability studies at refrigerating conditions.
6.	3.2.P.1	• Justification shall be submitted for proposed fill weight per vial of Ertapenem sodium considering the actual content of sodium declared in the drug substance analysis and content of sodium bicarbonate in the drug substance. • Details of accompanying reconstitution diluent shall be submitted.
7.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
8.	3.2.P.6	Justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium.

9.	3.2.P.8	Documents for the procurement of API with approval from DRAP.

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

Oral Dry Powder for suspension(Penicillin)

564.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying oral dry powder for suspension (Penicillin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 20848 dated 23-08-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 358853822803
	The proposed proprietary name / brand name	**Flemicillin 125 mg/5mL Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Ampicillin Trihydrate eq to Ampicillin…… 125mg
	Pharmaceutical form of applied drug	Penicillin antibiotics
	Pharmacotherapeutic Group of (API)	White to off white well homogenized powder free from extraneous matter filled in ambered glass bottle sealed with pp cap, neatly labelled and packed in a unit carton with insertion of a leaflet, plastic measuring cup 20ml, and plastic spoon 5ml, on reconstitution with 40ml of water, off white suspension with sweet taste is availed.
	Reference to Finished product specifications	BP
	Proposed Pack size	60ml, 100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ampicillin 125 mg Suspension (MHRA Approved)
	For generic drugs (me-too status)	Ampistal Suspension of M/s Stallion pharmaceuticals (Reg # 077228).
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Ampistal Suspension 125 mg manufactured by Stallion pharmaceutical (PVT) LTD by performing quality tests Description, Identification, pH, Microbial contamination, Deliverable volume, Assay,
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.		
API Lot No.	00003/070/2021		
Description of Pack (Container closure system)	FPP is packed in ambered colored glass bottle, further packed in unit carton along with patient leaflet insert		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	1666 bottles	1666 bottles	1666 bottles
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	22-04-2022	23-04-2022	25-04-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) issued by DRAP on the basis of evaluation conducted on 22-06-2022 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted instead of drug product in accordance to BP monograph.
5.	3.2.S.7	Justification is required for not performing the identification test, pH and determination of optical rotation during the stability study of drug substance
6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
7.	3.2.P.5.2	Concentrations of standard and sample solution as per BP monograph is 0.06mg/ml while your concentration for standard and sample are 0.6mg/ml. Clarify.
8.	3.2.P.5.3	Concentrations used for standard and sample are not as per BP monograph in analytical method verification. Clarification is required.
9.	3.2.P.6	• BP monograph specified use of anhydrous Ampicillin as reference standard while you have provided COA of Ampicillin Trihydrate as reference standard. Clarification is required. • Submit COA of reference standard Cefradine as per BP monograph.
10.	3.2.P.8	Purchase documents for Ampicillin trihydrate from Drug substance manufacturer.

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

M/s Pasteur and Fleming pharma. **(New DML)**

CLB in its 283rd meeting held on 28th October 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five (05) sections to M/s Pasteur and Fleming pharma

3) Tablet (Hormone)
4) Tablet (General)
5) Capsule (General)
6) Dry Powder Suspension (General)

7) Cream/Ointment Section (General)		
565.	Name, address of Applicant / Marketing Authorization Holder	Pasteur and Fleming pharma Plot No. P.70-A, Phase 3, Road No. 04, Industrial Area Hattar
	Name, address of Manufacturing site.	Pasteur and Fleming pharma Plot No. P.70-A, Phase 3, Road No. 04, Industrial Area Hattar
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Trackin Id: JJG-86L-ENVQ Application No. 465 dated 16-11-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 79628608092
	The proposed proprietary name / brand name	PASMIT 50/500MG TABLET
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sitagliptin as phosphate monohydrate……50mg Metformin hydrochloride..... 500mg
	Pharmaceutical form of applied drug	Antifungal
	Pharmacotherapeutic Group of (API)	Film coated tablet
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Janumet Tablet 50/500 by Merck Sharp & Dohme Corp, USA of (USFDA Approved)
	For generic drugs (me-too status)	Treviamet Tablet of M/s Getz Pharma.
	Name and address of API manufacturer.	**Sitagliptin Phosphate Monohydrate:** M/s Fuxin Long Rui Pharmaceutical CO.,Ltd. Fluoride Industrial Park, Fumeng County(Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hydrochloride:** M/s. Aarti Drugs Limited. Plot No. 211 - 213, Road No.2, G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sitagliptin Phosphate Monohydrate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 24 months. **Metformin Hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Janumet by performing quality tests Identification, Weight variation, Disintegration Time, Uniformity of dosage unit , Dissolution, Assay. CDP has been performed against the 'Janumet Tablets in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Sitagliptin Phosphate Monohydrate:** M/s Fuxin Long Rui Pharmaceutical CO.,Ltd. Fluoride Industrial Park, Fumeng County(Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hydrochloride:** M/s. Aarti Drugs Limited. Plot No. 211 - 213, Road No.2, G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155
API Lot No.	**Sitagliptin Phosphate Monohydrate:** L-D06-CP11422014 **Metformin Hydrochloride:** MEF/12030815
Description of Pack	Alu-alu blister

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	15-03-2023	16-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin Phosphate Monohydrate:** Letter for API's Loan from M/s Seraph Pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # E-5186186525926, dated; 04-05-2023 specifying Invoice No # HN230314S-E dated: 22-03-2022 Sitagliptin Phosphate Monohydrate batch #. L-D06-CP11422014 (Seraph Pharmaceuticals). **Metformin Hydrochloride:** Letter for API's Loan from M/s Seraph Pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # E-1760286526132, dated; 01-07-2022 specifying Invoice No # EXP/602/22-23 dated: 26-05-2022 Metformin Hydrochloride batch # MEF/12030815 (Seraph Pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.5.5	Submit Correct pharmacological group with submission of requisite fee.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer for Sitagliptin phosphate & Metformin hydrochloride issued by relevant regulatory authority of country of origin
3.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	3.2.S.4.1	BP Specification are claimed for Metformin HCl however, Certificate of analysis provided as per USP monograph by drug product manufacturer.

5.	3.2.S.4.2	Assay method for Metformin HCl by drug product manufacturer is not as specified in the BP monograph. Clarification is required.
6.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance (Metformin HCl) shall be submitted
7.	3.2.S.4.4	• Drug substance manufacturer of Metformin HCl claimed BPSpecifications but you have submitted Certificate of analysis as per USP Specifications. Clarification is required. • Assay limits of Metformin HCl are not mentioned in COA by drug product manufacturer.
8.	3.2.S.5	COA of primary / secondary reference standard including source and lot number for Metformin HCl shall be provided
9.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product i.e Lactose monohydrate and Primojel.
10.	3.2.P.2.2.1	Time points in Comparative dissolution method are 05, 15, and 30minutes while in data time points are 10, 15, 20, and 30 minutes. Clarification is required for difference in time points.
11.	3.2.P.6	COA of primary / secondary reference standard including source and lot number for both Sitagliptin phosphate and Metformin HCl shall be provided
12.	3.2.P.8	Manufacturing of stability batches conducted in March 2023 while approval of Metformin HCL from DRAP in May 2023. Clarification is required.

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

566.	Name, address of Applicant / Marketing Authorization Holder	Pasteur and Fleming pharma Plot No. P.70-A, Phase 3, Road No. 04, Industrial Area Hattar
	Name, address of Manufacturing site.	Pasteur and Fleming pharma Plot No. P.70-A, Phase 3, Road No. 04, Industrial Area Hattar
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Tablet (General) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Trackin Id: 6LV-3QY-R3RG Application No. 466 dated 16-11-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 930814440
	The proposed proprietary name / brand name	PASMIT 50/1000MG TABLET
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sitagliptin as phosphate monohydrate……50mg Metformin hydrochloride..... 1000mg
	Pharmaceutical form of applied drug	Antidiabetic
	Pharmacotherapeutic Group of (API)	Film coated tablet
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Janumet Tablet 50/1000 by Merck Sharp & Dohme Corp, USA of (USFDA Approved)
	For generic drugs (me-too status)	Treviamet Tablet of M/s Getz Pharma.
	Name and address of API manufacturer.	**Sitagliptin Phosphate Monohydrate:** M/s Fuxin Long Rui Pharmaceutical CO.,Ltd. Fluoride Industrial Park, Fumeng County(Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hydrochloride:** M/s. Aarti Drugs Limited. Plot No. 211 - 213, Road No.2, G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sitagliptin Phosphate Monohydrate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 24 months. **Metformin Hydrochloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Janumet by performing quality tests Identification, Weight

		variation, Disintegration Time, Uniformity of dosage unit , Dissolution, Assay. CDP has been performed against the 'Janumet Tablets in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sitagliptin Phosphate Monohydrate:** M/s Fuxin Long Rui Pharmaceutical CO.,Ltd. Fluoride Industrial Park, Fumeng County(Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hydrochloride:** M/s. Aarti Drugs Limited. Plot No. 211 - 213, Road No.2, G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . INDIA.396155		
API Lot No.	**Sitagliptin Phosphate Monohydrate:** L-D06-CP11422014 **Metformin Hydrochloride:** MEF/12030815		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2023	03-2023	03-2023
Date of Initiation	15-03-2023	16-03-2023	17-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin Phosphate Monohydrate:** Letter for API's Loan from M/s Seraph Pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # E-5186186525926, dated; 04-05-2023 specifying Invoice No # HN230314S-E dated: 22-03-2022 Sitagliptin Phosphate Monohydrate batch #. L-D06-CP11422014 (Seraph Pharmaceuticals). **Metformin Hydrochloride:** Letter for API's Loan from M/s Seraph Pharmaceuticals submitted. Firm has submitted copy of Clearance certificate # E-1760286526132, dated; 01-07-2022 specifying Invoice No # EXP/602/22-23 dated: 26-05-2022 Metformin Hydrochloride batch # MEF/12030815 (Seraph Pharmaceuticals)

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

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer for Sitagliptin phosphate & Metformin hydrochloride issued by relevant regulatory authority of country of origin
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	3.2.S.4.1	BP Specification are claimed for Metformin HCl however, Certificate of analysis provided as per USP monograph by drug product manufacturer.
4.	3.2.S.4.2	Assay method for Metformin HCl by drug product manufacturer is not as specified in the BP monograph. Clarification is required.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance (Metformin HCl) shall be submitted
6.	3.2.S.4.4	• Drug substance manufacturer of Metformin HCl claimed BP Specifications but you have submitted Certificate of analysis as per USP Specifications. Clarification is required. • Assay limits of Metformin HCl are not mentioned in COA by drug product manufacturer.
7.	3.2.S.5	COA of primary / secondary reference standard including source and lot number for Metformin HCl shall be provided
8.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product i.e Lactose monohydrate and Primojel.
9.	3.2.P.2.2.1	Time points in Comparative dissolution method are 05, 15, and 30minutes while in data time points are 10, 15, 20, and 30 minutes. Clarification is required for difference in time points.
10.	3.2.P.5.2	In analytical testing method of assay, in sample solution preparation how 500mg Metformin HCl makes 1mg/ml of concentration.
11.	3.2.P.6	COA of primary / secondary reference standard including source and lot number for both Sitagliptin phosphate and Metformin HCl shall be provided
12.	3.2.P.8	• Manufacturing of stability batches conducted in March 2023 while approval of Metformin HCL from DRAP in May 2023. Clarification is required. • In raw data of both Accelerated and Real time stability studies at all time points concentration of Metformin HCl used is 0.5mg/ml while in analytical testing method Concentration of Metformin HCl mentioned is 1.0mg/ml. Clarification is required.

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

b. New/Additional section(s)

Deferred case

M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore

CLB in its 273rd meeting held on 15th January 2020, has approved the following 3 additional sections of M/s British Pharmaceuticals

1.Capsule Section (General)
2.Dry Powder Section (General)
3.Tablet Section (General)

567.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20289 dated 18-07-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 86328899583
	The proposed proprietary name / brand name	Bricit 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains:- Cetirizine Dihydrochloride ……10mg
	Pharmaceutical form of applied drug	White oblong shape film coated tablet
	Pharmacotherapeutic Group of (API)	Histamine Receptor Antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's, 2x10's, 10x10's, Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cetirizine film coated tablets of MHRA Approved
	For generic drugs (me-too status)	Histex 10mg Tablet M/s Pharmatec Pakistan, Reg. No. 020342
	GMP status of the Finished product manufacturer	Renewal of DML granted dated 12-01-2022.
	Name and address of API manufacturer.	M/s Sreekara Organics Plot No. 159/A, S.V. Co-op. Ind. Estate India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cetirizine Dihydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: CZ/V/00611, CZ/V/00511, CZ/V/00411)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Rigix 10mg tablet by AGP Pharma. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Bricit 10mg tablet by British Pharma in Acid media (pH 1.0-1.2) Acetate buffer (pH 4.5)& Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Sreekara Organics Plot No. 159/A, S.V. Co-op. Ind. Estate India		
API Lot No.	CTZ03521		
Description of Pack (Container closure system)	Alu-Pvc blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B1	B2	B3
Batch Size	24000 Tablets	24000 Tablets	24000 Tablets
Manufacturing Date	26-08-2021	26-08-2021	26-08-2021
Date of Initiation	27-08-2021	27-08-2021	27-08-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate # L.Dis.No:82408/TS/2022 issued by Drug Control Administration Governament of Telangana issued on 15-03-2022 and valid until 14-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 3, 5 ,7 from & invoice (invoice# ZHI-CI/5465/0621) dated: 26-06-2021 cleared by DRAP Lahore office dated 12-07-2021 specifying import 100Kg Cetirizine 2HCl (Batch# CTZ03521

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

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	Valid Drug Manufacturing License Or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	2.3.R.1.1	In manufacturing of stability batches production Overage of Cetirizine 2HCl is Used. Clarification is required.	Overage was not used in stability batches. There was a calculation error observed in the manufacturing order. Revised document is attached.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the British Pharmaceuticals for drug substance(s) instead of drug product shall be submitted.	Analytical Method Verification studies including accuracy and repeatability performed by theBritish Pharmaceuticals for drug substance(s) are submitted. But specificity not submitted.
4.	3.2.S.4.4	In COA of drug substance by drug product manufacturer Residue on ignition and loss on drying are mentioned as complies and ok. Clarify.	Revised COA is attached with values of Residue on ignition and loss on drying.
5.	3.2.P.5.2	The manufacturer shall mention dissolution test No as per requirement of USP monograph.	Dissolution Test 1 was used for testing of the product.
6.	3.2.P.5.3	Performance of accuracy & precision parameter during analytical method verification studies has not been conducted as per recommendations of ICH Q2 (R1) guidelines. Specificity is not done for drug product	**No reply submitted.**

Previous Decision (M-326): Deferred for submission of following**:**

- Performance of Specificity parameter in the analytical method verification studies of drug substance by drug product manufacturer.
- Analytical method verification studies of drug product .

S.No	Reason of deferment	Reply
1.	Performance of Specificity parameter in the analytical method verification studies of drug substance by drug product manufacturer.	Specificity parameter in the analytical method verification studies of drug substance by drug product manufacturer performed and submitted.
2.	Analytical method verification studies of drug product.	Analytical method verification studies of drug product Submitted.

Decision: Approved with USP specifications.

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

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

1.Oral liquid Section (General) Additional

568.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3222 dated 03-02-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 708047908
	The proposed proprietary name / brand name	Temol Suspension 120mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol…….120mg
	Pharmaceutical form of applied drug	Clear, viscous liquid light orange to orange colour
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 120 mg/5 ml Oral Suspension by Pinewood Laboratories Limited, Ireland of MHRA approved.
	For generic drugs (me-too status)	Calpol Pediatric Suspension of M/s GlaxosmithKline Pakistan. No.000354
	GMP status of the Finished product manufacturer	Copy of cGMP certificate on the basis of Evaluation conducted on 04-01-2022 and valid for two years.

	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol(Actaminophen) is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol Suspension by M/s GSK Batch # 372R by performing quality tests (description, Identification, pH, Deliverable Volume, Viscosity, Microbial Enumeration, Assay)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
API Lot No.	21GN60187
Description of Pack (Container closure system)	Clear, viscous liquid light orange to orange colour sweet in taste filled in ambered glass bottle of USP type III sealed with Aluminium cap, neatly labelled and packed in a unit carton with insertion of a leaflet
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)

Batch No.	T-006	T-007	T-008
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	10-12-2021	10-12-2021	10-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of cGMP certificate on the basis of evaluation conducted on 07-10-2022 and valid for 02 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.2	In Assay final concentrations is 0.01mg/ml while 96 mg of paracetamol from oral suspension taken. Clarify how from 96mg 0.01mg/ml concentration prepared.
4.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
5.	3.2.P.8	Purchase Documents for Paracetamol. Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Previous Decision (M-327): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation:

S. No	Section	Shortcomings Communicated	Reply
	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3	The revised precision parameter of analytical method verification of drug substance is attached.

		concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).	
	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.	The testing of reference product was performed as per claimed product specifications (BP Specs). Temol suspension was built on USP specifications during the product development phase. However revised pharmaceutical equivalence according USP specifications is submitted.
	3.2.P.5.2	In Assay final concentrations is 0.01mg/ml while 96 mg of paracetamol from oral suspension taken. Clarify how from 96mg 0.01mg/ml concentration prepared.	It was typo error .The revised analytical method is submitted. 100mg of paracetamol from oral suspension taken.
	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).	The revised precision parameter of analytical method verification of drug product is submitted.
	3.2.P.8	• Purchase Documents for Paracetamol. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• The API was locally purchased. Purchased documents of paracetamol are attached.(Invoice #PRT/2021/0185 dated: 29-07-2021) • Compliance record of HPLC software 21 CFR & audit trail reports on product testing

Previous Decision (M-330): Deferred for following clarifications:

- Manufacturing facility along with details of equipment's wherein the trial batches have been manufactured along with evidence of approval of required manufacturing facility from CLB.
- Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.

- Equipment list along with Syrup Section approval from CLB submitted.
- Firm submitted stability data of 03 new batches.

Batch No.	T-10	T-11	T-12
Batch Size	10 Liters	10 Liters	10 Liters
Manufacturing Date	January 2023	January 2023	January 2023
Date of Initiation	07-01-2023	07-01-2023	07-01-2023

Evaluation by PEC:

- Registration Board in its 330th meeting held on 24th July to 26th July 2023 deferred your product for following
- "Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies." However, no clarification/justification of above has been provided.
- 330th meeting of Registration Board was held on 24th July to 26th July 2023 wherein, above Clarification/justification was asked, however, you have manufactured new batches in January-2023. Justification is required.
- Details of equipment's along with their capacity wherein new trial batches have been
- Manufactured.

• Submit details of drug substance used for manufacturing of new stability batches, including batch Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided. • Compliance Record of HPLC software 21CFR & audit trail reports on new batches of product testing..		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
569.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7379 dated 14-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 3924666116
	The proposed proprietary name / brand name	Temol DS Suspension 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol…….250mg
	Pharmaceutical form of applied drug	Clear, viscous liquid light orange to orange colour
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 250 mg/5 ml Oral Suspension by Pinewood Laboratories Limited, Ireland of MHRA approved.
	For generic drugs (me-too status)	Calpol 6 plus Suspension of M/s GlaxosmithKline Pakistan. No.000354
	GMP status of the Finished product manufacturer	Copy of cGMP certificate on the basis of Evaluation conducted on 04-01-2022 and valid for two years.
	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol(Actaminophen) is present in USP. The firm as submitted detail of nomenclature, structure, general properties,

		solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Calpol 6 Plus Suspension by M/s GSK Batch # 372R by performing quality tests (description, Identification, pH, Deliverable Volume, Viscosity, Microbial Enumeration, Assay)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.		
API Lot No.	21GN60187		
Description of Pack (Container closure system)	Clear, viscous liquid light orange to orange colour sweet in taste filled in ambered glass bottle of USP type III sealed with Aluminium cap, neatly labelled and packed in a unit carton with insertion of a leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-007	T-008	T-009
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	20-06-2022	22-06-2022	24-06-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of cGMP certificate on the basis of evaluation conducted on 07-10-2022 and valid for 02 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
4.	3.2.P.8	Purchase Documents for Paracetamol. Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Previous Decision (M-327): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).	The revised precision parameter of analytical method verification of drug substance is attached.
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.	The testing of reference product was performed as per claimed product specifications (BP Specs). Temol suspension was built on USP specifications during the product development phase. However revised pharmaceutical equivalence according USP specifications is submitted.
3.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates	The revised precision parameter of analytical method verification of drug product is submitted.

		each) while you have used 6 determinations (3 concentrations /2 replicates each).	
4.	3.2.P.8	• Purchase Documents for Paracetamol. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• The API was locally purchased. Purchased documents of paracetamol are attached.(Invoice #PRT/2021/0185 dated: 29-07-2021) • Compliance record of HPLC software 21 CFR & audit trail reports on product testing

Previous Decision (M-330): Deferred for following clarifications:

- Manufacturing facility along with details of equipment's wherein the trial batches have been manufactured along with evidence of approval of required manufacturing facility from CLB.
- Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.

- Equipment list along with Syrup Section approval from CLB submitted.
- Firm submitted stability data of 03 new batches.

Batch No.	T-11	T-12	T-13
Batch Size	10 Liters	10 Liters	10 Liters
Manufacturing Date	January 2023	January 2023	January 2023
Date of Initiation	14-01-2023	14-01-2023	14-01-2023

Evaluation by PEC:

- Registration Board in its 330th meeting held on 24th July to 26th July 2023 deferred your product for following
- "Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies." However, no clarification/justification of above has been provided.
- 330th meeting of Registration Board was held on 24th July to 26th July 2023 wherein, above Clarification/justification was asked, however, you have manufactured new batches in January-2023. Justification is required.
- Details of equipment's along with their capacity wherein new trial batches have been
- Manufactured.
- Submit details of drug substance used for manufacturing of new stability batches, including batch Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided.
- Compliance Record of HPLC software 21CFR & audit trail reports on new batches of product testing..

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

Case no. 02 Contract manufacturing application as per decision of 173rd meeting of Authority
Deferred case:

570.	Name, address of Applicant / Marketing Authorization Holder	M/s ICI Pakistan Limited. ICI House, 5 West Wharf Karachi
	Name, address of Manufacturing site.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	M/s ICI Pakistan Limited: Firm has submitted copy of GMP certificate dated 04-06-2022 based on

		inspection conducted on 06-06-2019 and valid until for 2 years . M/s Pharmasol: Firm has submitted copy of GMP certificate dated 22-04-2020 based on inspection conducted on 13-02-2020 and valid until for one years
	Evidence of approval of manufacturing facility	Firm has submitted copy issuance of DML letter (Pharmasol) specifying DRY Powder Injection (General)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33808 dated 05-09-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip# 2528891659
	The proposed proprietary name / brand name	Polem Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium (Powder for Reconstitution) 80mg eq to of 34mg of Colsitin
	Pharmacotherapeutic Group of (API)	Anti bacterial for systemic use, Polymyxin
	Pharmaceutical form of applied drug	Powder for injection
	Reference to Finished product specifications	USP specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colistimethate Sodium 1 million I.U. Powder for Solution for Injection. (MHRA Approved)
	For generic drugs (me-too status)	Coliate injection 1MIU by M/s High-Q Pharmaceuticals
	Name and address of API manufacturer.	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5% for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% for 6 months Batches: (CMS1802001, CMS1802002 & CMS1802003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Colomycin injection 1 million IU of M/s Teva, UK by performing quality tests (Identification, pH, free colistin, Loss on drying, Completeness an clarity of solution, s clarity of solution, Assay, and Bacterial Endotoxin).
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA		
Manufacturer of API	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd.	
API Lot No.	CMS2110005	
Description of Pack (Container closure system)	Alu-Alu	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	KC001	KC002
Batch Size	11000	11000
Manufacturing Date	09-2018	11-2018
Date of Initiation	03-10-2018	16-11-2018
No. of Batches	03	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Purchase invoice # FXIN1806291M dated: 18-12-2020 Cleared by DRAP (Lahore) dated: 17-08-2018 Specifying 02Kg of Colistimethate Sodium batch # CMS1803004

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

Remarks of Evaluator:

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	3.2.S.4.1	Copies of the Drug substance specifications /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
6.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
7.	3.2.P.5.2	• What is Standard concentration S_3 and how it is prepared. • Justify your sample preparation for assay in Analytical testing method with reference to USP monograph. • Medium used is different than medium used in USP monograph for bioassay. Clarify.
8.	3.2.P.8	Documents for the procurement Of drug substance show different batch No than submitted COA.

Previous Decision (M-331): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Copy of DMLNo. 20160089 issued by NMPA of china valid till 21/9/2025.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 submitted.
3.	3.2.S.4.1	Copies of the Drug substance specifications /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Copies of the Drug substance specifications /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug	Analytical procedures used for routine testing of the Drug substance /Active

		substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	As the colistime Injection is a sterile Dry powder for injection. In the manufacturing of the Colistime Injection the sterile bulk is received from the manufacturer and then filled aseptically in the selected container closure system. There is no addition of any excipient in the finished product so the AMV performed for the colistime Injection is also applicable for the Colistimethate Sodium.
6.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product	Compatibility studies with WFI submitted.
7.	3.2.P.5.2	• What is Standard concentration S_3 and how it is prepared. • Justify your sample preparation for assay in Analytical testing method with reference to USP monograph. • Medium used is different than medium used in USP monograph for bioassay. Clarify.	• Weigh Accurately Colistimethate Sodium working standard equal to 100mg of Colistimethate base in a 10ml volumetric flask. Add 5ml distilled water sonicate for 15 minutes. Then make up volume with water. Take 5ml from 1st dilution in a 50ml volumetric flask make up volume with phosphate buffer pH 6.00. Take 1ml from 2nd dilution in a 100ml volumetric flask make up volume with phosphate buffer pH 6.00. Take 15.7ml from 3rd dilution in a 100ml volumetric flask make up volume with phosphate buffer pH 6.00. Prepare from stock solution four standard dilution the successive solution increases stepwise in concentration usually in a ratio of 1:1.25 • Constitute Colistimethate for injection with 2ml of sterile water for injection (40mg/ml). take 1.25ml from reconstituted injection in 50ml volumetric flask and mak up volume with phosphate buffer of pH 6.0 (1st Dilution)(1mg/ml). Then take 0.1 ml from 1st dilution in 100ml volumetric flask and make up volume with phosphate buffer pH 6.0 (1µg/ml) , U_3 Median concentration. • Mueller-Hinton agar is commonly used for Bio-assay. It has been recommended by the CLSI (Clinical and Laboratories standards institute) as the ideal medium for antibiotics susceptibility testing. It shows good reproducibility from batch to batch.

	3.2.P.8	Documents for the procurement Of drug substance show different batch No than submitted COA.	Firm submitted COA of drug substance batch No# CMS1803004 by both drug substance manufacturer and drug product manufacturer in accordance to import documents as in BMR's batch No# CMS1803004 was used.	

Firm submitted fee of Rs: 67500/- Deposit slip # 1073304864 and Rs: 7500/- Deposit slip # 55652644 for change of name from ICI Pakistan Limited to Lucky Core Industries Limited.

Decision: Approved with USP specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter**

Case no. 03 Registration applications of import cases

a. Deferred cases

i. Human

571.	Name, address of Applicant / Importer	M/s Genome Pharma, House no. 166-A St. # 9, Chaklala Scheme III, Rawalpindi.
	Details of Drug Sale License of importer	DSL No.: 01-374-0176-035673D Address: Genome Pharma, House no. 166-A St. # 9, Chaklala Scheme III, Rawalpindi. Godown: C-19, main commercial, access road, R RCCI Industrial estat rawat, Rawalpindi. Validity: 28/08/2022 Status: license to sell drugs as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Republican Unitary Production Enterprise "Blemedpreparaty", 220007, Minsk, 30 Fabritsius St., Belarus.
	Name, address of manufacturer(s)	M/s Republican Unitary Production Enterprise "Blemedpreparaty", 220007, Minsk, 30 Fabritsius St., Belarus. Manufacturing activities: 30 Fabritsius, 1/22 Mayakovsky st., 7 Betonnyi Passage, Minsk, Republic of Belarus.
	Exporting country	Belarus
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized CoPP (certiifcate No. 109-2019/CPP/PK) issued by Ministry of Health Belarus on 17/09/2019. The applied product is present in the market of exporting country for free sale. The facilities and operations conform to WHO-GMP. • Original legalized GMP certificate No. 073/2018/GMP valid till 28/05/2021 issued by Ministry of Health, Belarus.	
	Details of letter of authorization / sole agency agreement • Notarized copy of product specific sole agency agreement is submitted.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 2653 Dated 22/01/2021
	Details of fee submitted	Rs. 100,000/- Dated 09/06/2020
	The proposed proprietary name / brand name	Pataxel Infusion 30mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial (5ml) contains: Paclitaxel..... 30mg
	Pharmaceutical form of applied drug	Oily clear colorless or yellowish liquid/concentrate for solution for infusion
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PACLITAXEL 6 mg/ ml, concentrate for solution for infusion (30mg/5ml vial & 100mg/16.7ml vial) by M/s Sindan, MHRA approved.
	For generic drugs (me-too status)	Taxol injection 30mg/5ml, Registration Number 16180
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 verification stduies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification studies of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co., Ltd., No. 508, Maodian road, Liantang, Qingpu dostrict Shaghai 201716, 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 verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	12 months real time stability data at 30˚C ± 2˚C / 60% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches

	Module-III Drug Product:	Submitted. Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is submitted against Paclitaxel Ebewe 30mg/5ml by Ebewe Pharma GmbH KG Austria.
	Analytical method validation/verification of product	Analytical methd verification studies are submitted.
	Container closure system of the drug product	Glass vial with rubber stopper and aluminium caps. Packed in unit carton.
	Stability study data of drug product, shelf life and storage conditions	• months real time stability data at 30˚C ± 2˚C / 65% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches

Evaluation by PEC-I:

Shortcomings	Response by the firm
Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted	Pharmaceutical equivalence is submitted against Paclitaxel Ebewe 30mg/5ml by Ebewe Pharma GmbH KG Austria.
A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided in section 3.2.P.7 under Container closure system.	Submitted.
Notarized product specific sole agency agreement is required.	Submitted.
Analytical Method Verification studies for Drug Substance performed by the Drug Product manufacturer	The firm has submitted method verification studies for drug substance including specificity, accuracy and repeatability (method precision) performed by drug product manufacturer.
Form-5F is from manufacturer/MAH abroad while it should be from the applicant holding the Drug Sale License.	The firm has submitted form 5F.
Real/long term stability data at 30˚C ± 2˚C / 60% ± 5%RH of 03 batches till shelf life of the applied product is required along with 06 months accelerated stability data at 40˚C ± 2˚C / 75% ± 5%RH in section 3.2.P.8 of module 3 including supporting documents (chromatograms, raw data sheets etc) and summary of the same in section 2.3.P.7 of module 2.	The firm has stated that the applied product is unstable when it is stored at 30ºC while the product is stable below 25ºC during full shelf life.
Scientific justification for selection of ascetic filling instead of terminal sterilization	The firm has stated that: The product is manufactured hermetically sealed insulator, with regular monitoring and all operations including filtration is carried out under ascetic conditions in insulators. (membrane filtes used with a pore size of 0.22um).

		The integrity of filter is check before and after filtration by diffusion flow method using Palltronic Flowstar IV device. Moreover, bioburden in each batch is monitored. The obtained results of validation test on retention capacity of the filter, filter integrity, tests during filtration correspond to the declared sterilizing level. The effectiveness of membrane filters was established by validating retention capacity of the sterilizing filter.	

Previous Decision (M-308): Deferred for submission of long term stability studies conducted according to the zone IV-A till shelf life

Firm submitted Accelerated stability studies for 6 month 40˚C ± 2˚C / 75% ± 5%RH and Real time stability studies data of 2 years at 30˚C ± 2˚C / 65% ± 5%RH of 03 batches.
070614, 181115, 010416

Decision: Approved with USP specifications as per Policy for inspection of Manufacturer abroad.

572.	Name, address of Applicant / Importer	M/s Genome Pharma, House no. 166-A St. # 9, Chaklala Scheme III, Rawalpindi.
	Details of Drug Sale License of importer	DSL No.: 01-374-0176-035673D Address: Genome Pharma, House no. 166-A St. # 9, Chaklala Scheme III, Rawalpindi. Godown: C-19, main commercial, access road, R RCCI Industrial estat rawat, Rawalpindi. Validity: 28/08/2022 Status: license to sell drugs as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Republican Unitary Production Enterprise "Blemedpreparaty", 220007, Minsk, 30 Fabritsius St., Belarus.
	Name, address of manufacturer(s)	M/s Republican Unitary Production Enterprise "Blemedpreparaty", 220007, Minsk, 30 Fabritsius St., Belarus. Manufacturing activities: 30 Fabritsius, 1/22 Mayakovsky st., 7 Betonnyi Passage, Minsk, Republic of Belarus.
	Exporting country	Belarus
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized CoPP (certiifcate No. 111-2019/CPP/PK) issued by Ministry of Health Belarus on 17/09/2019. The applied product is present in the market of exporting country for free sale. The facilities and operations conform to WHO-GMP. • Original legalized GMP certificate No. 073/2018/GMP valid till 28/05/2021 issued by Ministry of Health, Belarus.	
	Details of letter of authorization / sole agency agreement • Notarized copy of product specific sole agency agreement is submitted.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging

		☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 2655 Dated 22/01/2021
	Details of fee submitted	Rs. 100,000/- Dated 09/06/2020
	The proposed proprietary name / brand name	Pataxel Infusion 100mg/16.7ml
	Strength/concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial (16.7ml) contains: Paclitaxel..... 100mg
	Pharmaceutical form of applied drug	Oily clear colorless or yellowish liquid/concentrate for solution for infusion
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PACLITAXEL 6 mg/ ml, concentrate for solution for infusion (30mg/5ml vial & 100mg/16.7ml vial) by M/s Sindan, MHRA approved.
	For generic drugs (me-too status)	CLITAXEL INJECTION 100MG/17ml, Reg No. 63959
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 verification stduies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification studies of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co., Ltd., No. 508, Maodian road, Liantang, Qingpu dostrict Shaghai 201716, 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 verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	12 months real time stability data at 30˚C ± 2˚C / 60% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of

		drug product, specifications, analytical procedures, verification studies of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is submitted against Paclitaxel Ebewe 100mg/16.7ml by Ebewe Pharma GmbH KG Austria.
	Analytical method validation/verification of product	Analytical method verification stdies are submitted.
	Container closure system of the drug product	Glass vial with rubber stopper and aluminium caps. Packed in unit carton.
	Stability study data of drug product, shelf life and storage conditions	• months real time stability data at 30°C ± 2°C / 65% ± 5%RH of 03 batches • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches

Evaluation by PEC-I:

Shortcomings	Response by the firm
Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted	Pharmaceutical equivalence is submitted against Paclitaxel Ebewe 100mg/16.7ml by Ebewe Pharma GmbH KG Austria.
A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided in section 3.2.P.7 under Container closure system.	Submitted.
Notarized product specific sole agency agreement is required.	Submitted.
Analytical Method Verification studies for Drug Substance performed by the Drug Product manufacturer	The firm has submitted method verification studies for drug substance including specificity, accuracy and repeatability (method precision) performed by drug product manufacturer.
Form-5F is from manufacturer/MAH abroad while it should be from the applicant holding the Drug Sale License.	The firm has submitted form 5F.
Real/long term stability data at 30°C ± 2°C / 60% ± 5%RH of 03 batches till shelf life of the applied product is required along with 06 months accelerated stability data at 40°C ± 2°C / 75% ± 5%RH in section 3.2.P.8 of module 3 including supporting documents (chromatograms, raw data sheets etc) and summary of the same in section 2.3.P.7 of module 2.	The firm has stated that the applied product is unstable when it is stored at 30°C while the product is stable below 25°C during full shelf life.
Scietific justification for selection of asceptic filling instead of terminal sterilization	The firm has stated that: The product is manufactured hermetically sealed insulator, with regular monitoring and all operations including filtration is carried out under asceptoc conditions in insulators. (membrane filtes used with a pore size of 0.22um). The integrity of filter is check before and after filtration by diffusion flow method using Palltronic Flowstar IV device. Moreover, bioburden in each batch is monitored. The obtained results of validation test on retention capacity of the filter, filter integrity, tests during filtration correspond to the declared sterilizing level.

	The effectiveness of membrane filters was established by validating retention capacity of the sterilizing filter.	
Previous Decision (M-308): Deferred for submission of long term stability studies conducted according to the zone IV-A till shelf life.		
Firm submitted Accelerated stability studies for 6 month 40˚C ± 2˚C / 75% ± 5%RH and Real time stability studies data of 2 years at 30˚C ± 2˚C / 65% ± 5%RH of 03 batches. 010310, 020410, 030410		
Decision: Approved with USP specifications as per Policy for inspection of Manufacturer abroad.		

Agenda of Evaluator PEC-III

Case No. 01 Registration applications of cases of PINSTECH

DRAP Authority in its **161st meeting** held on April 5 and 6, 2023 while considering the request of PINSTECH decided to grant 6 months relaxation under SRO 713(I)/2018 from Form 5F (CTD) for following 8 applications.

The decision of Authority was communicated vide letter F. No. 1-2/2022-DMC on 12th June 2023.

Furthermore, DRAP Authority in its 177th meeting decided as under:

"In order to ensure the availability of rediopharmaceutical therapies in the country, decided to consider requests of registration of following molecules through registration board on priority/ out of queue.

1. **PINSCAN-MAG-3**
2. **PINSCAN-MDP**
3. **PINSCAN Pyrophosphate**
4. **PINSCAN DTPA**
5. **PINSCAN MIBI**
6. **ADENOSINE**
7. **PAKGEN TC-99M Generator**
8. **IODINE-131"**

Accordingly, the following applications have been received and evaluated and presented before the Board for consideration.

573.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	PINSCAN MAG-3 Lyophilized powder for injection
	Composition	Each vial contains: Betiatide……1mg
	Diary No. Date of R& I & fee	Dy. No 28494: 11-12-2023 PKR. 75,000/-: 11-12-2023
	Pharmacological Group	For dynamic renal scan study

	Type of Form	Form 5D
	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	Rs. 1500 / Vial, 5's
	Approval status of product in Reference Regulatory Authorities.	**TGA Australia** (Technescan MAG 3 Kit for preparation of Technitium 99m Tc mertiatide powder for injection multidose vial
	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.
	Clinical indications of Reference product	For use in the preparation of Technetium TC99m mertiatide for use as a renal imaging agent and for estimating split renal function. INDICATIONS AS AT 19 JULY 2001: Technetium Tc 99m mertiatide is a renal imaging agent for use in the diagnosis of congenital and acquired abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatric patients. (See Pediatric Use.) It is a diagnostic aid in providing renal function, split function, renal angiograms, and renogram curves for whole kidney and renal cortex.
	Remarks of the Evaluator[3].	• GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.** • **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**	
574.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	PINSCAN MDP Lyophilized powder for injection
	Composition	Each vial contains: Medronic acid……10mg
	Diary No. Date of R& I & fee	Dy. No 28495: 11-12-2023 PKR. 75,000/-: 11-12-2023
	Pharmacological Group	Bone imaging agent
	Type of Form	Form 5D
	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	Rs. 1500 / Vial
	Approval status of product in Reference Regulatory Authorities.	**TGA Australia** RADPHARM MDP kit for the production of Technetium (99mTc) medronate powder for injection multidose vial

	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.
	Clinical indications of Reference product	INDICATIONS AS AT 25 SEPTEMBER 1996: Technetium (99mTc) medronate may be used as a skeletal imaging pharmaceutical.
	Remarks of the Evaluator[3].	• GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.** • **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**	
575.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	PINSCAN Pyrophosphate Lyophilized powder for injection
	Composition	Each vial contains: Sodium pyrophosphate……12mg
	Diary No. Date of R& I & fee	Dy. No 28496: 11-12-2023 PKR. 75,000/-: 11-12-2023
	Pharmacological Group	Blood pool imaging agent, cardiac and skeletal imaging agent.
	Type of Form	Form 5D
	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	Rs. 1500 / Vial
	Approval status of product in Reference Regulatory Authorities.	CIS-PYRO TECHNETIUM TC-99M PYROPHOSPHATE KIT **(USFDA Approved)**
	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.
	Clinical indications of Reference product	Bone imaging agent used to demonstrate areas of altered osteogenic and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction
	Remarks of the Evaluator[3].	• GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.** • **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**	

576.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	PINSCAN DTPA Lyophilized powder for injection
	Composition	Each vial contains: Pentetic acid……10mg
	Diary No. Date of R& I & fee	Dy. No 28497: 11-12-2023 PKR. 75,000/-: 11-12-2023
	Pharmacological Group	For dynamic renal scan and brain study
	Type of Form	Form 5D
	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	Rs. 1500 / Vial
	Approval status of product in Reference Regulatory Authorities.	**TGA Australia** PENTASTAN Kit for preparation of Technetium(99mTc) pentetate powder for injection
	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.
	Clinical indications of Reference product	99mTc-Pentastan may be used to perform kidney-imaging, brain imaging, to assess renal perfusion and estimate glomeruler filtration rate
	Remarks of the Evaluator[3].	• GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.** • **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**	
577.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	PINSCAN MIBI Lyophilized powder for injection
	Composition	Each vial contains: Tetrakis(2-methoxyisobutylisonitrile) copper(1) tetrafluoroborate……1mg
	Diary No. Date of R& I & fee	Dy. No 28498: 11-12-2023 PKR. 75,000/-: 11-12-2023
	Pharmacological Group	As adjunct in the diagnosis of ischemic heart disease
	Type of Form	Form 5D

	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	Rs. 6000 / Vial
	Approval status of product in Reference Regulatory Authorities.	**TGA Australia** TECHNESCAN SESTAMIBI kit for the preparation of technetium [99m Tc] sestamibi injection
	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.
	Clinical indications of Reference product	Technetium [99m Tc] Sestamibi is indicated for use in conjunction with stress testing as an adjunct in the diagnosis of ischaemic heart disease. In these patients additional information about ventricular function may be derived by using the first pass technique. Technetium [99m Tc]Sestamibi is indicated as a second line diagnostic aid to assistin the evaluation of patients for whom mammography is inconclusive.
	Remarks of the Evaluator[3].	• GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.** • **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**	
578.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	PINSCAN Adenosine 30mg/10ml Sterile solution for injection
	Composition	Each 10ml vial contains: Adenosine……30mg (3.0mg/ml)
	Diary No. Date of R& I & fee	Dy. No 28499: 11-12-2023 PKR. 75,000/-: 11-12-2023
	Pharmacological Group	Coronary vasodilator for intravenous use
	Type of Form	Form 5D
	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	Rs. 2500 / Vial
	Approval status of product in Reference Regulatory Authorities.	**TGA Australia** ADENOVIEW adenosine 30 mg/10 mL solution for injection vial
	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.

	Clinical indications of Reference product	ADENOVIEW is a coronary vasodilator for intravenous use in conjunction with radionuclide myocardial perfusion imaging, in patients unable to exercise adequately.
	Remarks of the Evaluator[3].	• GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.** • **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**	
579.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	PAKGEN^{99} Mo/^{99}m Tc Generator Injectable (Elute from Tc-99m generator with 0.9% Saline and labeled with freeze dried cold kit)
	Composition	Sodium pertechnetate [^{99m}Tc], 18.5 GBq to 37 GBq
	Diary No. Date of R& I & fee	Dy. No 28500: 11-12-2023 PKR. 75,000/-: 11-12-2023
	Pharmacological Group	Diagnostic radiopharmaceutical
	Type of Form	Form 5D
	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	37MBQ (1mCi): Rs 400 per mCi
	Approval status of product in Reference Regulatory Authorities.	**TGA Australia** TECHNELITE Molybdenum(99Mo)/Technetium(99mTc) sterile Generator for production of Sodium pertechnetate(99mTc) injection multidose vial
	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.
	Clinical indications of Reference product	Technetium [99mTc] generator is used for the preparation of Sodium Pertechnetate 99m Tc injection. SodiumPertechnetate 99mTc is used as an agent for: Brain Imaging, Thyroid Imaging, Salivary Gland Imaging, Blood Pool Imaging..
	Remarks of the Evaluator[3]. • GMP inspection report conducted within a period of last three years. • The reference product is approved as under:	

Pack Size/Poison information

Pack Size	Poison Schedule
74.0 GBq	Not scheduled. Not considered by committee
370 GBq	Not scheduled. Not considered by committee
111 GBq	Not scheduled. Not considered by committee
18.5 GBq	Not scheduled. Not considered by committee
27.8 GBq	Not scheduled. Not considered by committee
277.5 GBq	Not scheduled. Not considered by committee
462.5 GBq	Not scheduled. Not considered by committee
185 GBq	Not scheduled. Not considered by committee
222 GBq	Not scheduled. Not considered by committee
55.5 GBq	Not scheduled. Not considered by committee
129.5 GBq	Not scheduled. Not considered by committee
148 GBq	Not scheduled. Not considered by committee
37.0 GBq	Not scheduled. Not considered by committee
46.3 GBq	Not scheduled. Not considered by committee
555 GBq	Not scheduled. Not considered by committee
64.8 GBq	Not scheduled. Not considered by committee
166.5 GBq	Not scheduled. Not considered by committee
92.5 GBq	Not scheduled. Not considered by committee

Components

1 . Medicine component

Dosage Form	Injection, solution
Route of Administration	Intravenous
Visual Identification	Clear, colourless solution

Active Ingredients

sodium pertechnetate(99mTc)	**18.5 GBq**

Decision: Approved with following label claim:

Sodium pertechnetate [99mTc]

Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.

- **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**

580.	Name and address of manufacturer / Applicant	M/s Pakistan Institute of Nuclear Science & Technology, Nilore Islamabad.
	Brand Name +Dosage Form + Strength	Sodium Iodide (^{131}I) Oral solution
	Composition	Each 6ml vial contains: Sodium Iodide (Na^{131}I)……150mCi (at standard caliberation date & time)
	Diary No. Date of R& I & fee	Dy. No 28501: 11-12-2023 PKR. 75,000/-: 11-12-2023

	Pharmacological Group	Radioisotopic drug used for imaging
	Type of Form	Form 5D
	Finished Product Specification	European pharmacopoeia
	Pack size & demanded price	Rs. 280 / mCi
	Approval status of product in Reference Regulatory Authorities.	**USFDA** SODIUM IODIDE I 131 SOLUTION THERAPEUTIC for oral use (Discontinued)
	Me-too status	NA
	GMP status	Inspection report of the firm dated 17-05-2017 wherein the panel recommended renewal of DML was presented by the firm.
	Clinical indications of Reference product	Sodium Iodide I 131 Solution Therapeutic is a radioactive therapeutic agent indicated for the treatment of hyperthyroidism and thyroid carcinomas that take up iodine. Palliative effects may be observed in patients with advanced thyroid malignancy if the metastatic lesions take up iodine

Remarks of the Evaluator[3].

- GMP inspection report conducted within a period of last three years.
- The reference product is approved as under:

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status
SODIUM IODIDE I 131	SODIUM IODIDE I-131	3.5-150mCi/VIAL	SOLUTION;ORAL	Discontinued
SODIUM IODIDE I 131	SODIUM IODIDE I-131	0.8-100mCi	CAPSULE;ORAL	Discontinued

Showing 1 to 2 of 2 entries

Sodium Iodide I 131 Solution Therapeutic		
NDC	**Volume of Solution**	**Total Radioactivity per Vial**
69945-450-01	1 mL	185 MBq (5 mCi)
69945-450-02	2 mL	370 MBq (10 mCi)
69945-450-03	3 mL	555 MBq (15 mCi)
69945-450-04	4 mL	740 MBq (20 mCi)
69945-450-05	5 mL	925 MBq (25 mCi)
69945-450-07	7 mL	1295 MBq (35 mCi)
69945-451-02	2 mL	1850 MBq (50 mCi)
69945-451-03	3 mL	2775 MBq (75 mCi)
69945-451-04	4 mL	3700 MBq (100 mCi)
69945-451-06	6 mL	5550 MBq (150 mCi)

11 DESCRIPTION

Sodium Iodide I 131 (Na I-131) Solution Therapeutic is supplied for oral administration as a stabilized aqueous solution. The solution is available in vials that contain from 185 to 5550 MBq (5 to 150 mCi) iodine-131 at the time of calibration. Sodium Iodide I 131 Solution Therapeutic is packaged in shielded, screw-cap 15 mL vials.

The solution contains 0.1% sodium bisulfite and 0.2% edetate disodium as stabilizers, 0.5% sodium phosphate anhydrous as a buffer and sodium iodide I-131 at concentrations of 185 or 925 MBq (5 or 25 mCi) per milliliter. The pH has been adjusted to between 7.5 and 9. The iodine-131 utilized in the preparation of the solution contains not less than 99% iodine-131 at the time of calibration. The expiration date is not later than one month after the calibration date. The calibration date and the expiration date are stated on the label.

Decision: Approved with the following claim

Sodium Iodide ($Na^{131}I$)

Firm will submit following documents and the Board Authorized its Chairman for issuance of registration letter.

- **Updated GMP certificate / inspection report of the firm conducted within a period of last three years.**

Case No. 02 Registration applications of Form 5 or Form 5-D submitted along with stability study data submitted before 31st December, 2022 as per decision of Authority.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
581.	M/s Scilife Pharma (Pvt.) Ltd Plot FD-57/58-A2 Korangi Creek Industrial Park Karachi	Eflozin 12.5/850 mg Tablet Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 37405 12-11-2018 PKR. 50,000/- 12-11-2018 As per SRO	Approved by EMA Firm has submitted copy of GMP certificate dated 07-03-2023 based on inspection conducted on 22-02-2023.

Date of submission of stability study data: 19-05-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park Fumeng County Liaoning Province China **Metformin:** Shouguang Fukang Pharmaceutical Co., Ltd North-east of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province China		
API Lot No.	**Empagliflozin:** E20190920-D02-E06-01 **Metformin:** A-32612004031		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	119B20	120B20	121B20

Batch Size	3000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	07-09-2020	07-09-2020	07-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Eflozin Tablet, for which the inspection was conducted on 27-09-2019 and the report was presented in 292nd meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone II conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML issued by CFDA China valid till 20-12-2022. **Metformin:** Firm has submitted copy of GMP certificate issued by CFDA China valid till 22-11-2021
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 30-01-2020 specifying 10Kg Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 16-06-2020 specifying 3000Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study

8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Xenglu-Met tablet of Hilton Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Submit stability study data of empagliflozin API as per zone IV-A conditions.

Decision: Deferred for following submissions:

- **Stability study data of empagliflozin API as per zone IV-A conditions.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**

582.	Name and address of manufacture / Applicant	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name + Dosage Form and Strength	Glusimet XR 100/1000 mg Tablets
	Composition	Each film-coated tablet contains: Sitagliptin Phosphate as Monohydrate…100mg Metformin HCl (extended release)…1000mg
	Dairy No. date of R &I fee	Dy No. 14973: 25.04.2018 PKR 20,000/-: 25.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	The firm has claimed manufacturer's specifications.
	Pack size and Demand Price	5x10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	JANUMET XR 50/1000 sitagliptin (as phosphate monohydrate)/metformin hydrochloride 50 mg/1000 mg extended release tablet. TGA approved
	Me-too-status	Tagipmet XR 100/500 Tablet. Reg. No. 84651
	GMP Status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP.
	Remark of the Evaluator	• The firm was asked to submit stability data of three batches conducted in Zone IV-A. The firm did not submit the same.

Decision of 290th meeting of Registration Board: Deferred for submission of stability data of of product as per decision of Registration Board.

Date of submission of stability study data: 01-03-2021

STABILITY STUDY DATA

Manufacturer of API	**Sitagliptin:** Zhejiang Yongtai Pharmaceutical Co td. Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone Linhai City, Zhejiang Province China **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India		
API Lot No.	**Sitagliptin:** 1827-0001-19080 **Metformin:** MEF19081813		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	013B20	014B20	015B20
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	20-04-2020	20-04-2020	20-04-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Eflozin Tablet, for which the inspection was conducted on 27-09-2019 and the report was presented in 292nd meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Sitagliptin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone II conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** Firm has submitted copy of GMP certificate issued by CFDA China valid till 03-05-2022. **Metformin:** Firm has submitted copy of GMP certificate issued by Food and Drugs Control Administration, Gujrat State India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin:** Firm has submitted copy of commercial invoice cleared dated 30-08-2019 specifying 150Kg API. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 30-09-2019 specifying 1500Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches

11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Tagipmet-XT tablet of Highnoon Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Submit stability study data of metformin API as per zone IV-A conditions.

Decision: Deferred for following submissions:

- **Stability study data of empagliflozin API as per zone IV-A conditions.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**

583.	Name and address of manufacture / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/ sector 27,Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form and Strength	Pirfen Tablets 267mg
	Composition	Each film coated tablet contains: Pirfenidone …267mg
	Dairy No. date of R &I fee	Diary No:16073, 25/09/2017, Rs: 50,000/- (Challan# 0577275, Dated: 25/09/2017)
	Pharmacological Group	Other immunosuppressants
	Type of form	Form 5-D
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	30‘s / As per SROAs per SRO.
	Approval status of product in Reference Regulatory Authorities	ESBRIET (pirfenidone) film-coated tablets 267mg by M/s Genentech, Inc. (USFDA Approved)
	Me-too-status	N/A

	GMP Status	Last GMP inspection of Getz Pharma is conducted on 05-07-2017 and the report concludes that firm was operating at an acceptable level compliance of GMP
	Remark of the Evaluator	• Firm has not submitted real time and accelerated stability study data for 3 batches as per Zone IV-A

Decision of 283rd meeting of Registration Board: Deferred for submission of stability study data along with associated documents as per the requirements of 278th meeting of Registration Board.

Date of submission of stability study data: 26-10-2021

STABILITY STUDY DATA

Manufacturer of API	M/s Optimus Drugs Private Limited, Sy. No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri - Bhuvanagiri District – 508 284, Telangana - India		
API Lot No.	OP-PIF-A1001/20		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	**556DS01**	**556DS02**	**556DS03**
Batch Size	2,500 tablets	2,500 tablets	2,500 tablets
Manufacturing Date	22-10-2020	23-10-2020	23-10-2020
Date of Initiation	06-11-2020	06-11-2020	06-11-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product for Estine (Ebastine) Tablets 10mg & 20mg on 6th May, 2019. Further, the said panel inspection report was discussed in 289th Drug Registration Board meeting held on 14th – 16th May 2019. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm.

		• Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by DCA Telangana State India dated 03-03-2020.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 29-09-2020 specifying 5Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the Mac-Fenid Tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted

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

Evaluation by PEC:

Decision: Approved with Innovator's specifications.

- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

584.	Name and address of manufacture / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/ sector 27,Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form and Strength	Pirfen Tablets 801mg
	Composition	Each film coated tablet contains: Pirfenidone …267mg
	Dairy No. date of R &I fee	Diary No:16072, 25/09/2017, Rs: 50,000/- (Challan# 0577274, Dated: 25/09/2017)
	Pharmacological Group	Other immunosuppressants
	Type of form	Form 5-D
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	30's / As per SROAs per SRO.
	Approval status of product in Reference Regulatory Authorities	ESBRIET (pirfenidone) film-coated tablets 801mg by M/s Genentech, Inc. (USFDA Approved)
	Me-too-status	N/A
	GMP Status	Last GMP inspection of Getz Pharma is conducted on 05-07-2017 and the report concludes that firm was operating at an acceptable level compliance of GMP
	Remark of the Evaluator	• Firm has not submitted real time and accelerated stability study data for 3 batches as per Zone IV-A

Decision of 283rd meeting of Registration Board: Deferred for submission of stability study data along with associated documents as per the requirements of 278th meeting of Registration Board.

Date of submission of stability study data: 26-10-2021

STABILITY STUDY DATA

Manufacturer of API	M/s Optimus Drugs Private Limited, Sy. No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri - Bhuvanagiri District – 508 284, Telangana - India

API Lot No.	OP-PIF-A1001/20		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	**557DS01**	**557DS02**	**557DS03**
Batch Size	1,500 tablets	1,500 tablets	1,500 tablets
Manufacturing Date	22-10-2020	23-10-2020	23-10-2020
Date of Initiation	06-11-2020	06-11-2020	06-11-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product for Estine (Ebastine) Tablets 10mg & 20mg on 6th May, 2019. Further, the said panel inspection report was discussed in 289th Drug Registration Board meeting held on 14th – 16th May 2019. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer

4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by DCA Telangana State India dated 03-03-2020.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 29-09-2020 specifying 5Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the Mac-Fenid Tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Firm has applied for Pirfen Tablets 801mg however in the minutes of 283rd meeting of Registration Board, the composition inadvertently specified 267mg strength.

Decision: Registration Board noted the information and decided to approved with Innovator's specifications with following correction in label claim.

Each film coated tablet contains:

Pirfenidone …801mg

- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
585.	M/s McOlson Research Laboratories (Pvt) Ltd Plot No 2, M-2, Pharmazone 26 KM Lahor Sharikpur Road Sheikhupura.	Esonap 500/20mg Tablet Each Double Core Tablet Contains: Naproxen (as enteric coated inner core)…500mg Esomeprazole (as magnesium trihydrate film coated immediate release outer core)……20mg (NSAID + PPI) In-house specifications	Form 5D Dy No. 1458 15-01-2011 PKR. 8,000/- 13-01-2011 + PKR 12000 24-11-2014 As per SRO	Approved by USFDA Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-06-2022.

Date of submission of stability study data: 11-10-2021

STABILITY STUDY DATA

Manufacturer of API	**Esomeprazole:** Metrochem API Pvt Ltd Unit-I Plot No. 62/C/6, Pipeline Road, Phase-I IDA Jeedimetla Mandal, Malkajgiri Telangana India. **Naproxen:** Divi's Laboratories Limited, Unit-II, Annavaram Visakhapatnam Andhra Pradesh India		
API Lot No.	**Esomeprazole:** ESM/1906234 **Naproxen:** 2-M-B-2050818		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	ENS-PB-02	ENS-PB-03	ENS-PB-04
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	02-11-2019	02-11-2019	02-11-2019

No. of Batches	03	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Detox Tablet, for which the inspection was conducted on 31-12-2021 & 11-01-2021 and the report was presented in 293rd meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Esomeprazole:** Firm has submitted stability study data of 3 batches of drug substance as per refrigerating conditions **Naproxen:**
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Esomeprazole:** Firm has submitted copy of GMP certificate issued by DCA Telangana India issued on 22-04-2020 **Naproxen:** Firm has submitted copy of GMP certificate dated 26-06-2021 issued by DCA Government of Andhra Pradesh.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Esomeprazole:** Firm has submitted copy of commercial invoice cleared dated 02-07-2019 specifying 15Kg API. The invoice is cleared by AD (I&E) DRAP. **Naproxen:** Firm has submitted copy of commercial invoice cleared dated 12-02-2019 specifying 6.5Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required

10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- CDP studies are not provided by the firm

Decision: Deferred for submission of comparative dissolution profile (CDP) studies with innovator / reference product.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability Me-too status GMP Inspection Report Date & Remarks
586.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Tenofojen Tablet 25mg Each Film Coated Tablet Contains: Tenofovir Alafenamid Fumarate…25mg (Anti-viral) In-house specifications	Form 5 Dy No. 15693 07-03-2019 PKR. 20,000/- 06-03-2019 As per SRO	Approved by USFDA Tefod Tablet by Sami Firm has submitted copy of last inspection report conducted on 04-06-2022 for grant of GMP certificate wherein it was concluded that the firm has maintained a good level of GMP compliance

Date of submission of stability study data: 15-03-2021

STABILITY STUDY DATA

Manufacturer of API	Shijiazhuang Lonzeal Pharmaceutical Co Ltd. Industrial Zone Shenze (No. 16 West Ring Road) China

API Lot No.	1900016091		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	TNJ-PB-025001	TNJ-PB-025002	TNJ-PB-025003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	28-04-2020	28-04-2020	28-04-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Lansodex Capsule, for which the inspection was conducted on 10-12-2018 and the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per refrigerating conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by CFDA China valid till 19-09-2024

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 20-03-2020 specifying 122g API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- CDP studies are not provided by the firm

Decision: Deferred for submission of comparative dissolution profile (CDP) studies with innovator / reference product.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
587.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Ertujen 5mg Tablet Each Film Coated Tablet Contains: Ertugliflozin As L Pyroglutamic Acid…5mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 16130 07-03-2019 PKR. 50,000/- 06-03-2019 As per SRO	Approved by USFDA Firm has submitted copy of last inspection report conducted on 04-06-2022 for grant of GMP certificate wherein it was concluded that the firm

				has maintained a good level of GMP compliance

Date of submission of stability study data: 26-04-2021

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Hongyuan Pharmaceutical Co Ltd. Chem & APIs Industrial Zone, Linhai Zhejiang China		
API Lot No.	ETG20191001		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	ERT-PB-026001	ERT-PB-026002	ERT-PB-026003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	19-05-2020	19-05-2020	19-05-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Lansodex Capsule, for which the inspection was conducted on 10-12-2018 and the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by CFDA China dated 15/03/2018.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 14-11-2019 specifying 200Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP

9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Firm has submitted that since innovator's product is not available in Pakistan therefore CDP studies was not conducted. Firm has requested to exempt this study.

Decision: Deferred for submission of comparative dissolution profile (CDP) studies with innovator / reference product.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
588.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Ertujen 15mg Tablet Each Film Coated Tablet Contains: Ertugliflozin As L Pyroglutamic Acid…15mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 16131 07-03-2019 PKR. 50,000/- 06-03-2019 As per SRO	Approved by USFDA Firm has submitted copy of last inspection report conducted on 04-06-2022 for grant of GMP certificate wherein it was concluded that the firm has maintained a good level of GMP compliance

Date of submission of stability study data: 26-04-2021

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Hongyuan Pharmaceutical Co Ltd. Chem & APIs Industrial Zone, Linhai Zhejiang China		
API Lot No.	ETG20191001		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	ERT-PB-027001	ERT-PB-027002	ERT-PB-027003

Batch Size		1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date		07-2020	07-2020	07-2020
Date of Initiation		19-07-2020	19-07-2020	19-07-2020
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Lansodex Capsule, for which the inspection was conducted on 10-12-2018 and the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer	
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by CFDA China dated 15/03/2018.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 14-11-2019 specifying 200Kg API. The invoice is cleared by AD (I&E) DRAP.	
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study	
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required	
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches	
11.	Record of comparative dissolution data (where applicable)	Not submitted	
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Evaluation by PEC:			
• Firm has submitted that since innovator's product is not available in Pakistan therefore CDP studies was not conducted. Firm has requested to exempt this study.			

Decision: Deferred for submission of comparative dissolution profile (CDP) studies with innovator / reference product.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
589.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen-M Tablet 5/850mg Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…850mg (Anti-diabetic) In-house specifications	Form 5 Dy No. 15697 07-03-2019 PKR. 20,000/- 06-03-2019 As per SRO	Approved by EMA Firm has submitted copy of last inspection report conducted on 04-06-2022 for grant of GMP certificate wherein it was concluded that the firm has maintained a good level of GMP compliance

Date of submission of stability study data: 11-10-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Chifeng Arker Pharmaceutical Technology Co Ltd. No 8, Mysun Street Hongshan Economic Development Zone Chifeng Inner Mangolia China. **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India		
API Lot No.	**Empagliflozin:** D86-191001 **Metformin:** MEF/18122461		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	EMJ-PB-022001	EMJ-PB-022002	EMJ-PB-022003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	25-05-2020	25-05-2020	25-05-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Lansodex Capsule, for which the inspection was conducted on 10-12-2018 and the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate issued by CFDA China dated 28/12/2020. **Metformin:** Firm has submitted copy of GMP certificate issued by Food and Drugs Control Administration, Gujrat State India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 08-11-2019 specifying 290g Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-02-2019 specifying 200Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Diampa-M tablet of Getz Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Evaluation by PEC:		
•		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
590.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen M Tablet 5/1000mg Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg (Anti-diabetic) In-house specifications	Form 5 Dy No. 15696 07-03-2019 PKR. 20,000/- 06-03-2019 As per SRO	Approved by EMA Firm has submitted copy of last inspection report conducted on 04-06-2022 for grant of GMP certificate wherein it was concluded that the firm has maintained a good level of GMP compliance

Date of submission of stability study data: 11-10-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Chifeng Arker Pharmaceutical Technology Co Ltd. No 8, Mysun Street Hongshan Economic Development Zone Chifeng Inner Mangolia China. **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India		
API Lot No.	**Empagliflozin:** D86-191001 **Metformin:** MEF/18122461		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	EMJ-PB-028001	EMJ-PB-028002	EMJ-PB-028003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	25-06-2020	25-06-2020	25-06-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Lansodex Capsule, for which the inspection was conducted on 10-12-2018 and the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate issued by CFDA China dated 28/12/2020. **Metformin:** Firm has submitted copy of GMP certificate issued by Food and Drugs Control Administration, Gujrat State India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 08-11-2019 specifying 290g Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-02-2019 specifying 200Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Diampa-M tablet of Getz Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Evaluation by PEC:		
•		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
591.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen M Tablet 12.5/850mg Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg (Anti-diabetic) In-house specifications	Form 5 Dy No. 15691 07-03-2019 PKR. 20,000/- 06-03-2019 As per SRO	Approved by EMA Firm has submitted copy of last inspection report conducted on 04-06-2022 for grant of GMP certificate wherein it was concluded that the firm has maintained a good level of GMP compliance

Date of submission of stability study data: 11-10-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Chifeng Arker Pharmaceutical Technology Co Ltd. No 8, Mysun Street Hongshan Economic Development Zone Chifeng Inner Mangolia China. **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India		
API Lot No.	**Empagliflozin:** D86-191001 **Metformin:** MEF/18122461		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	EMJ-PB-029001	EMJ-PB-029002	EMJ-PB-029003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	26-06-2020	26-06-2020	26-06-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Lansodex Capsule, for which the inspection was conducted on 10-12-2018 and the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate issued by CFDA China dated 28/12/2020. **Metformin:** Firm has submitted copy of GMP certificate issued by Food and Drugs Control Administration, Gujrat State India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 08-11-2019 specifying 290g Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-02-2019 specifying 200Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Diampa-M tablet of Getz Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

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Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name	Type of Form,	International Availability

		(Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	GMP Inspection Report Date & Remarks
592.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen M Tablet 12.5/1000mg Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg (Anti-diabetic) In-house specifications	Form 5 Dy No. 15692 07-03-2019 PKR. 20,000/- 06-03-2019 As per SRO	Approved by EMA Firm has submitted copy of last inspection report conducted on 04-06-2022 for grant of GMP certificate wherein it was concluded that the firm has maintained a good level of GMP compliance

Date of submission of stability study data: 11-10-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Chifeng Arker Pharmaceutical Technology Co Ltd. No 8, Mysun Street Hongshan Economic Development Zone Chifeng Inner Mangolia China. **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India		
API Lot No.	**Empagliflozin:** D86-191001 **Metformin:** MEF/18122461		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	EMJ-PB-030001	EMJ-PB-030002	EMJ-PB-030003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	25-06-2020	25-06-2020	25-06-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Lansodex Capsule, for which the inspection was conducted on 10-12-2018 and the report was presented in 287th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate issued by CFDA China dated 28/12/2020. **Metformin:** Firm has submitted copy of GMP certificate issued by Food and Drugs Control Administration, Gujrat State India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 08-11-2019 specifying 290g Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-02-2019 specifying 200Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Diampa-M tablet of Getz Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Evaluation by PEC:		
•		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
593.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif 5mg Tablets Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. To Dapagliflozin…5mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 21957 23-11-2017 PKR. 50,000/- 22-11-2017 As per SRO	Approved by EMA

Date of submission of stability study data: 04-05-2021

STABILITY STUDY DATA

Manufacturer of API	Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China.		
API Lot No.	20191201		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	T01	T02	T03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	27-02-2020	27-02-2020	27-02-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Sovir Tablet, for which the inspection was conducted on 06-02-2017 and the report was presented in 279th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued by CFDA China valid till 29-11-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 30-12-2019 specifying 103Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of theinnovator's product therefore compatibility studies arenot required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Xiga tablet of CCL
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers	Submitted

	(real time and accelerated)	

Evaluation by PEC:

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Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
594.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif 10mg Tablets Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. To Dapagliflozin…10mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 21958 23-11-2017 PKR. 50,000/- 22-11-2017 As per SRO	Approved by EMA

Date of submission of stability study data: 04-05-2021

STABILITY STUDY DATA

Manufacturer of API	Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China.
API Lot No.	20191201
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)

Batch No.	T01	T02	T03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	27-02-2020	27-02-2020	27-02-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Sovir Tablet, for which the inspection was conducted on 06-02-2017 and the report was presented in 279th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued by CFDA China valid till 29-11-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 30-12-2019 specifying 103Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of theinnovator's product therefore compatibility studies arenot required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Xiga tablet of CCL

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
595.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif-M 5/850mg Tablets Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. To Dapagliflozin…5mg Metformin Hydrochloride…850mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 21959 23-11-2017 PKR. 50,000/- 22-11-2017 As per SRO	Approved by EMA

Date of submission of stability study data: 04-05-2021

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin:** Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China. **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India

API Lot No.	**Dapagliflozin:** 20191201 **Metformin:** MEF/18122464		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	T01	T02	T03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	22-03-2020	22-03-2020	22-03-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Sovir Tablet, for which the inspection was conducted on 06-02-2017 and the report was presented in 279th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Dapagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of DML issued by CFDA China valid till 29-11-2024.

		Metformin: Firm has submitted copy of GMP certificate issued by FDCA Gujrat India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** Firm has submitted copy of commercial invoice cleared dated 30-12-2019 specifying 103Kg API. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 16-05-2019 specifying 200Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of theinnovator's product therefore compatibility studies arenot required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Dapa-Met tablet of Hilton Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Evaluation by PEC:		
•		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
596.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif-M 5/1000mg Tablets Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. To Dapagliflozin…5mg Metformin Hydrochloride…1000mg (Anti-diabetic) In-house specifications	Form 5D Dy No. 21960 23-11-2017 PKR. 50,000/- 22-11-2017 As per SRO	Approved by EMA

Date of submission of stability study data: 04-05-2021

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin:** Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China. **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India		
API Lot No.	**Dapagliflozin:** 20191201 **Metformin:** MEF/18122464		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	T01	T02	T03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	03-2020	03-2020	03-2020

Date of Initiation		22-03-2020	22-03-2020	22-03-2020
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
1.	Reference of previous approval of applications with stability study data of the firm		Last PSI was conducted for Sovir Tablet, for which the inspection was conducted on 06-02-2017 and the report was presented in 279th meeting of Registration Board. The report confirms following points: • The HPLC software is not 21CFR compliant. • Yes audit trail can be seen from the software and were shown by the firm on screen	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.		Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer		Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer	
4.	Stability study data of API from API manufacturer		**Dapagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		**Dapagliflozin:** Firm has submitted copy of DML issued by CFDA China valid till 29-11-2024. **Metformin:** Firm has submitted copy of GMP certificate issued by FDCA Gujrat India dated 20-03-2020	
6.	Documents for the procurement of API with approval from DRAP (in case of import).		**Dapagliflozin:** Firm has submitted copy of commercial invoice cleared dated 30-12-2019 specifying 103Kg API. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 16-05-2019 specifying 200Kg Metformin. The invoice is cleared by AD (I&E) DRAP.	
7.	Protocols followed for conduction of stability study		Firm has submitted protocols followed for conduction of stability study	
8.	Method used for analysis of FPP		Firm has provided detailed method for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)		Firm has used same excipients as that of theinnovator's product therefore compatibility studies arenot required	

10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Dapa-Met tablet of Hilton Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

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Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
597.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Paineze 75mg Tablet Each Film Coated Tablet Contains: Tapentadol (as HCl)…75mg (Other opioids) In-house specifications	Form 5D Dy No. 839 10-02-2015 PKR. 20,000/- 06-02-2015 As per SRO	Approved by USFDA cGMP certificate on the basis of evaluation conducted on dated 12.08.2022

Date of submission of stability study data: 09-04-2021

STABILITY STUDY DATA

Manufacturer of API	Ami Lifesciences Pvt Ltd 82/B, ECP Road AT & Post Karakhadi Tal Padra Karakhadi Vadora Gujrat State India

API Lot No.	TPT/50020319		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2020	07-2020	07-2020
Date of Initiation	29-06-2020	14-07-2020	20-07-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Xetine Tablet", which was conducted on 03-03-2020, and was presented in 294th meeting of Registration Board.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP Certificate issued by FDCA (Gujrat State) dated 25-04-2019.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of license to import and invoice dated 15-01-2019 specifying 7.35Kg API.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP

9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studiesare not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Tapento IR Tablet of Sami Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Duplicate dossier was submitted which was sent to R&I for verification, R&I section has submitted that "The application for Paineze Tablet was received in R&I section of DRAP on 10-02-2015. Representative of the pharma has also produced the original receiving. However, staff has made the entry of R&I register vide Dy No 839 on same date but company name was mentioned "Wilson" instead of "Werrick" Extract taken from R&I section is attached for ready reference"
- Firm has submitted copy of 20,000 fee, while the application was submitted on Form 5D.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit balance fee since the application was submitted on Form 5D and the fee of 20,000 was submitted.**
- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group,	Type of Form, Initial Diary & Date, Fee (including differential fee),	International Availability

		Finished Product Specification	Demanded Price / Pack size	GMP Inspection Report Date & Remarks
598.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Rofscot 500mcg Tablet Each Tablet Contains: Roflumilast…500Mcg (Other systemic drugs for obstructive airway diseases) In-house specifications	Form 5D Dy No. 3699 28-01-2019 PKR. 50,000/- 28-01-2019 As per SRO	Approved by USFDA Firm has submitted copy of GMP certificate dated 17-12-2020 based on inspection conducted on 09-11-2020.

Date of submission of stability study data: 09-06-2021

STABILITY STUDY DATA

Manufacturer of API	Glenmark Pharmaceuticals Ltd Plot No A-80, MIDC Kukumbh Taluka Daund District Pune Mahrashtra India		
API Lot No.	83170223		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	18-04-2018	18-04-2018	18-04-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Dascot Tablet", which was conducted on 26-01-2018, and was presented in 278th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP Certificate issued by FDA (Maharashtra State) dated 28-01-2020.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 19-02-2018 specifying 10g API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of theinnovator's product therefore compatibility studies arenot required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Daliresp
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

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Decision: Approved with Innovator's specifications.

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

- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

599.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 12.5mg Tablets
	Composition	Each film coated tablet contains; Milnacipran HCl……12.5mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 249 dated 25.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. <u>Differential fee:</u> Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 2000501 dated 31-01-2020, endorsed on 31.01.2020. <u>Duplicate Dossier:</u> Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	Form-5D
	Finished product Specification	Scotmann Specs.
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.

	Decision of 326th meeting of Registration Board: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

Date of submission of stability study data: 15-03-2021

STABILITY STUDY DATA

Manufacturer of API	MSN Pharmachem Pvt Ltd Plot No 212 / ABCD Phase II, IDA Pashmylaram Patancheru Medak Sangareddy Telangana India		
API Lot No.	ME0010518		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	21-05-2019	22-05-2019	23-05-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Dascot Tablet", which was conducted on 26-01-2018, and was presented in 278th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer

4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm as submitted Copy of GMP Certificate issued by Drugs Control Administration (Telangana) dated 21-02-2018.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 13-06-2018 specifying 1.4Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

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Decision: Approved with Innovator's specifications.

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

600.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498)

		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 25mg Tablets
	Composition	Each film coated tablet contains; Milnacipran HCl……25mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 250 dated 27.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. <u>Differential fee:</u> Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927655 dated 31-01-2020, endorsed on 31.01.2020. <u>Duplicate Dossier:</u> Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	**Form-5D**
	Finished product Specification	**Scotmann Specs.**
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision of 326th meeting of Registration Board: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	

Date of submission of stability study data: 15-03-2021			
STABILITY STUDY DATA			
Manufacturer of API	MSN Pharmachem Pvt Ltd Plot No 212 / ABCD Phase II, IDA Pashmylaram Patancheru Medak Sangareddy Telangana India		
API Lot No.	ME0010518		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	24-05-2019	25-05-2019	26-05-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Dascot Tablet", which was conducted on 26-01-2018, and was presented in 278th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory	Firm as submitted Copy of GMP Certificate issued by Drugs Control Administration (Telangana) dated 21-02-2018.

	authority of country of origin.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 13-06-2018 specifying 1.4Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Decision: Approved with Innovator's specifications.

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

601.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 50mg Tablets
	Composition	Each film coated tablet contains;

		Milnacipran HCl……50mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 257 dated 27.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927654 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	**Form-5D**
	Finished product Specification	**Scotmann Specs.**
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision of 326th meeting of Registration Board: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	

Date of submission of stability study data: 15-03-2021

STABILITY STUDY DATA

Manufacturer of API	MSN Pharmachem Pvt Ltd Plot No 212 / ABCD Phase II, IDA Pashmylaram Patancheru Medak Sangareddy Telangana India
API Lot No.	ME0010518

Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	28-05-2019	29-05-2019	30-05-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Dascot Tablet", which was conducted on 26-01-2018, and was presented in 278th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm as submitted Copy of GMP Certificate issued by Drugs Control Administration (Telangana) dated 21-02-2018.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 13-06-2018 specifying 1.4Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study

8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with Innovator's specifications.

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

602.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 100mg Tablets
	Composition	Each film coated tablet contains; Milnacipran HCl……100mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 252 dated 25.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. <u>Differential fee:</u>

		Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 2000502 dated 31-01-2020, endorsed on 31.01.2020. <u>Duplicate Dossier:</u> Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	Form-5D
	Finished product Specification	Scotmann Specs.
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision of 326th meeting of Registration Board: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	

Date of submission of stability study data: 15-03-2021

STABILITY STUDY DATA

Manufacturer of API	MSN Pharmachem Pvt Ltd Plot No 212 / ABCD Phase II, IDA Pashmylaram Patancheru Medak Sangareddy Telangana India
API Lot No.	ME0010518
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months

Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	01-06-2019	02-06-2019	03-06-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Dascot Tablet", which was conducted on 26-01-2018, and was presented in 278th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm as submitted Copy of GMP Certificate issued by Drugs Control Administration (Telangana) dated 21-02-2018.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 13-06-2018 specifying 1.4Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches

11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with Innovator's specifications.

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

603.		
	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt.) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Sofosol 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Sofosbuvir..... 400mg
	Dairy No. date of R &I fee	Dy. No 23948 dated 11-07-2018 Fee Rs: 20,000/- dated 27-06-2018
	Pharmacological Group	Nucleotide Analog Inhibitor
	Type of form	Form 5
	Finished product specifications	Innovator
	Pack size and Demand Price	14's x 2 Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities	Sovaldi (Sofosbuvir 400mg) tablets, USFDA approved.
	Me-too-status	Sofohil Tablet by Hilton Pharma
	GMP Status	GMP certificate issued based upon inspection conducted in 26-08-2022

Date of submission of stability study data: 24-05-2021

STABILITY STUDY DATA			
Manufacturer of API	Ruyuan HEC Pharma Co.Ltd Xiaba Develeopment Zone, Ruyuan County, Shaoguan City, Guangdong Province, 512721, China		
API Lot No.	S104A-RD201902203		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	FJ001	FJ002	FJ003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	06-09-2019	06-09-2019	06-09-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML (No. 20170622) dated 20-12-2022 issued by Food and Drugs Administration China.

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 20-06-2019 specifying 8.42Kg API.The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Myhep Tablet of Mylan Laboratories
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

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

604.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt.) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Sofosol-V 400/100mg Tablet
	Composition	Each Film Coated Tablet Contains: Velpatasvir..... 100mg Sofosbuvir..... 400mg
	Dairy No. date of R &I fee	Dy. No 23950 dated 11-07-2018 Fee Rs: 20,000/- dated 27-06-2018

	Pharmacological Group	Nucleotide Analog Inhibitor / HCV NS5A Inhibitors
	Type of form	Form 5
	Finished product specifications	Innovator
	Pack size and Demand Price	14's x 02 Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities	Epclusa 400/100mg Tablet (Ledipasvir, Sofosbuvir) tablets, EU approved.
	Me-too-status	HilvelTablet by Hilton Pharma
	GMP Status	GMP certificate issued based upon inspection conducted in 26-08-2022

Date of submission of stability study data: 24-05-2021

STABILITY STUDY DATA

Manufacturer of API	**Sofosbuvir:** Ruyuan HEC Pharma Co.Ltd Xiaba Develeopment Zone, Ruyuan County, Shaoguan City, Guangdong Province, 512721, China **Velpatasvir:** Ruyuan HEC Pharma Co.Ltd Xiaba Develeopment Zone, Ruyuan County, Shaoguan City, Guangdong Province, 512721, China		
API Lot No.	**Sofosbuvir:** S104A-RD201902203 **Velpatasvir:** VEPII-201903004		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	EJ001	EJ002	EJ003
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	23-09-2019	23-09-2019	23-09-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Sofosbuvir:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Velpatasvir:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sofosbuvir:** Firm has submitted copy of DML (No. 20170622) dated 20-12-2022 issued by Food and Drugs Administration China. **Velpatasvir:** Firm has submitted copy of DML (No. 20170622) dated 20-12-2022 issued by Food and Drugs Administration China.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sofosbuvir:** Firm has submitted copy of commercial invoice cleared dated 20-06-2019 specifying 8.42Kg API. The invoice is cleared by AD (I&E) DRAP. **Velpatasvir:** Firm has submitted copy of commercial invoice cleared dated 20-06-2019 specifying 1.42Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Myhep Tablet 400/100mg

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

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

605.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt.) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Sofosol-L 90/400mg Tablet
	Composition	Each Film Coated Tablet Contains: Sofosbuvir..... 400mg Ledipasvir (Copovidone solid dispersion)..... 90mg
	Dairy No. date of R &I fee	Dy. No 23949 dated 11-07-2018 Fee Rs: 20,000/- dated 27-06-2018
	Pharmacological Group	Nucleotide Analog Inhibitor / HCV NS5A Inhibitors
	Type of form	Form 5
	Finished product specifications	Innovator
	Pack size and Demand Price	14’s x 02 Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities	Harvoni 90/400mg Tablet (Ledipasvir, Sofosbuvir) tablets, EU approved.
	Me-too-status	Harvoni Tablet by Ferozesons
	GMP Status	GMP certificate issued based upon inspection conducted in 26-08-2022

Date of submission of stability study data: 24-05-2021

STABILITY STUDY DATA

Manufacturer of API	**Sofosbuvir:** Ruyuan HEC Pharma Co.Ltd Xiaba Develeopment Zone, Ruyuan County, Shaoguan City, Guangdong Province, 512721, China **Ledipasvir:** Ruyuan HEC Pharma Co.Ltd Xiaba Develeopment Zone, Ruyuan County, Shaoguan City, Guangdong Province, 512721, China		
API Lot No.	**Sofosbuvir:** S104A-RD201902203 **Ledipasvir:** YAXII-201902002		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	LJ001	LJ002	LJ003
Batch Size	2400 tablets	2400 tablets	2400 tablets
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	18-09-2019	18-09-2019	18-09-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Sofosbuvir:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Ledipasvir:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sofosbuvir:** Firm has submitted copy of DML (No. 20170622) dated 20-12-2022 issued by Food and Drugs Administration China. **Ledipasvir:** Firm has submitted copy of DML (No. 20170622) dated 20-12-2022 issued by Food and Drugs Administration China.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sofosbuvir:** Firm has submitted copy of commercial invoice cleared dated 20-06-2019 specifying 8.42Kg API. The invoice is cleared by AD (I&E) DRAP. **Ledipasvir:** Firm has submitted copy of commercial invoice cleared dated 20-06-2019 specifying 1.38Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Myhep Tablet 90/400mg
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

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

606.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt.) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.

	Brand Name + Dosage Form and Strength	Daklavin Tablet 60mg
	Composition	Each Film Coated Tablet Contains: Daclatasvir as Dihydrochloride……60mg
	Dairy No. date of R &I fee	Dy. No 23932 dated 11-07-2018 Fee Rs: 20,000/- dated 27-06-2018
	Pharmacological Group	Biphenyls/ potent inhibitor of nonstructural protein 5A
	Type of form	Form 5
	Finished product specifications	In-house
	Pack size and Demand Price	07's x 4 Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities	Daklinza 60mg Tablet (Daclatasvir), EU standards approved.
	Me-too-status	Clavir Tablet by Hilton Pharma
	GMP Status	GMP certificate issued based upon inspection conducted in 26-08-2022

Date of submission of stability study data: 24-05-2021

STABILITY STUDY DATA

Manufacturer of API	Anhui Haikang Pharmaceutical Co. Ltd No.21 Huancheng West Road, Anqing, Anhui., 246000, China		
API Lot No.	20110505		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	UQ-T1	UQ -T2	UQ -T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	02-2021	02-2021	02-2021

Date of Initiation		13-02-2021	13-02-2021	13-02-2021
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
1.	Reference of previous approval of applications with stability study data of the firm		No PSI inspection of the firm has been conducted	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.		Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer		Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer	
4.	Stability study data of API from API manufacturer		Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Firm has submitted copy of DML valid till 31-12-2025 issued by Food and Drugs Administration China.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of commercial invoice cleared dated 01-01-2021 specifying 500g API. The invoice is cleared by AD (I&E) DRAP.	
7.	Protocols followed for conduction of stability study		Firm has submitted protocols followed for conduction of stability study	
8.	Method used for analysis of FPP		Firm has provided detailed method for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)		Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required	
10.	Complete batch manufacturing record of three stability batches.		Firm has provided Batch Manufacturing Record for all the batches	
11.	Record of comparative dissolution data (where applicable)		Firm has submitted CDP results of their product against Mydekla Tablet of Mylan Laboratories	
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.		Submitted	

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

Decision: Approved with Innovator's specifications.

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

607.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt.) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Dilazone 5mg Tablet
	Composition	Each Film Coated Tablet Contains Metolazone 5mg
	Dairy No. date of R &I fee	Dy. No 23933 dated 11-07-2018 Fee Rs: 20,000/- dated 27-06-2018
	Pharmacological Group	Thiazide Diuretics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's x 5 Alu-PVC Blister
	Approval status of product in Reference Regulatory Authorities	Zaroxolyn 5mg Tablet (Metolazone) tablets, USFDA standards approved.
	Me-too-status	Metxone Tablet by Genome
	GMP Status	GMP certificate issued based upon inspection conducted in 26-08-2022

Date of submission of stability study data: 24-05-2021

STABILITY STUDY DATA

Manufacturer of API	Centaur Pharmaceuticals (Pvt) Ltd Plot No. 75, 76 & 76/1 Chikhloli MIDC Ambernath Thane Maharashtra State India.
API Lot No.	1903602P
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH

	Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	MJ001	MJ002	MJ003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	04-08-2019	04-08-2019	04-08-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 02-08-2017 issued by Food and Drugs Administration Mahrashtra India.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 20-06-2019 specifying 500g API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required

10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Zaroxolyn Tablet of Teofarma Italy
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

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

608.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Cinacalsol Tablets 60mg
	Composition	Each film-coated tablet contains: Cinacalcet (as hydrochloride)…60mg
	Dairy No. date of R &I fee	Diary No: 24280 , 13-12-2017 , Rs: 20,000/-
	Pharmacological Group	Other anti-parathyroid agents
	Type of form	Form 5
	Finished product specifications	Innovator's specifications.
	Pack size and Demand Price	10's/ As per SRO
	Approval status of product in Reference Regulatory Authorities	Cinacalcet 60 mg film-coated tablets by M/s Bristol Laboratories Ltd (MHRA Approved)
	Me-too-status	Mimcipar tablet 60mg by M/s Genome Pharma (Reg#082302)
	GMP Status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.

	Remark of the Evaluator	•

Decision of 278th meeting of Registration Board: Deferred for submission of stability data as per format decided in instant meeting.

Date of submission of stability study data: 30-03-2021

STABILITY STUDY DATA

Manufacturer of API	Fuan Pharmaceutical Group Co. Ltd Huanan Yi Road, Changshou District Chongqing 401254, P.R.China		
API Lot No.	L-1703190101		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	BJ001	BJ002	BJ003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	29-07-2019	29-07-2019	29-07-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML issued by CFDA China valid till 04-08-2026
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 06-05-2019 specifying 1kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Mimcipar 60mg
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved.

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

609.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Carsevel Tablets 800mg
	Composition	Each film-coated tablet contains: Sevelamer Carbonate (MS).....800mg

	Dairy No. date of R &I fee	Diary No: 23931 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Pharmacological Group	Phosphate binder
	Type of form	Form 5
	Finished product specifications	Manufacturer specification.
	Pack size and Demand Price	30's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Renvela by Sanofi (MHRA)
	Me-too-status	Genovel Tablet by Genome Pharma (Reg. No. 085528)
	GMP Status	Last GMP inspection conducted on 29-05-2017, 30-05-2017 & 13-07-2017, 03-04-2017 and report concludes that panel recommends the grant of drug manufacturing license.
	Remark of the Evaluator	• Accelerated and Long term stability studies for 3 batches along with requisite documents.

Decision of 278th meeting of Registration Board: Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.

Date of submission of stability study data: 12-07-2021

STABILITY STUDY DATA

Manufacturer of API	Century Pharmaceuticals Ltd 103-106 GIDC Halol Panchmahal India		
API Lot No.	09468004-SLC		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	UU-T1	UU-T2	UU-T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	27-11-2020	27-11-2020	27-11-2020

No. of Batches		03
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by FDA Gujrat India dated 04-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 07-02-2020 specifying 7kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Renvela Tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers	Submitted

	(real time and accelerated)	

Decision: Approved with Innovator's specifications.

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

610.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Canazin 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin as Hemihydrate…300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40654 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK02
	Type of form	Form 5
	Finished product specifications	Manufacturer specification.
	Pack size and Demand Price	7's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	INVOKANA (canagliflozin) tablets USFDA Approved with box warning.
	Me-too-status	NA
	GMP Status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remark of the Evaluator	• It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.

Decision of 295th meeting of Registration Board: Deferred for submission of stability study data of applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.

Date of submission of stability study data: 12-12-2021			
STABILITY STUDY DATA			
Manufacturer of API	Huainan Shunlong Pharmaceutical Co.Ltd NO.9th Yongxing Road, Huainan Economic and Technological Development Zone, Huainan City, China		
API Lot No.	20201001		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	UZ-T1	UZ-T2	UZ-T3
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	17-07-2021	17-07-2021	17-07-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by CFDA China dated 04-03-2020

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 05-01-2021 specifying 1kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Invokana Tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with Innovator's specifications.

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

611.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Glyfozin-M 12.5mg/500mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…12.5mg Metformin HCl…500mg

	Dairy No. date of R &I fee	Dy.No 40562 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	Inhouse.
	Pack size and Demand Price	7's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	SYNJARDY® (empagliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too-status	NA
	GMP Status	08-07-2019 & 25-07-2019 Recommendations: The firmM/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping inview the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remark of the Evaluator	• It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.

Decision of 295th meeting of Registration Board: Deferred for submission of stability study data of applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.

Date of submission of stability study data: 22-12-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park Fumeng County Liaoning Province China **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India
API Lot No.	**Empagliflozin:** E-20190920-D02-E06-01 **Metformin:** MEF/10010078
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months

	Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	PJ-T1	PJ-T2	PJ-T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	21-09-2020	21-09-2020	21-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML issued by CFDA China valid till 20-12-2022. **Metformin:** Firm has submitted copy of GMP certificate issued by FDCA Gujrat India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 14-01-2020 specifying 0.5Kg Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 20-01-2020 specifying 50Kg Metformin. The invoice is cleared by AD (I&E) DRAP.

7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Xenglu-Met tablet of Hilton Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with Innovator's specifications.

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

612.	Name and address of manufacture / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form and Strength	Glyfozin-M 12.5mg/1000mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…12.5mg Metformin HCl…1000mg
	Dairy No. date of R &I fee	Dy.No 40563 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs

	Type of form	Form 5
	Finished product specifications	Inhouse.
	Pack size and Demand Price	7's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	SYNJARDY® (empagliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too-status	NA
	GMP Status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remark of the Evaluator	• It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.

Decision of 295th meeting of Registration Board: Deferred for submission of stability study data of applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.

Date of submission of stability study data: 22-12-2021

STABILITY STUDY DATA

Manufacturer of API	**Emagliflozin:** Fuxin Long Rui Pharmaceutical Co Ltd Fluoride Industrial Park Fumeng County Liaoning Province China **Metformin:** Aarti Drugs Limited Plot No 211 & 213 Road-2 GIDC AT & Post Sarigam Valsad Gujrat India
API Lot No.	**Empagliflozin:** E-20190920-D02-E06-01 **Metformin:** MEF/10010078
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)

Batch No.	RJ-T1	RJ-T2	RJ-T3
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	21-09-2020	21-09-2020	21-09-2020
No. of Batches	03		

	DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
1.	Reference of previous approval of applications with stability study data of the firm	No PSI inspection of the firm has been conducted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions **Metformin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of DML issued by CFDA China valid till 20-12-2022. **Metformin:** Firm has submitted copy of GMP certificate issued by FDCA Gujrat India dated 20-03-2020
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice cleared dated 14-01-2020 specifying 0.5Kg Empagliflozin. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 20-01-2020 specifying 50Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP

9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Xenglu-Met tablet of Hilton Pharma
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

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Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
613.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Dyspenal Tablet Each Fim Coated Tablet Contains: Acotiamide Hydrochloride Hydrate…100mg (Propulsives) In-house specifications	Form 5D Dy No. 1151 09-01-2018 PKR. 50,000/- 27-12-2017 As per SRO	Approved by PMDA Japan

Date of submission of stability study data: 28-10-2021

STABILITY STUDY DATA			
Manufacturer of API	Precise Chemipharma Pvt Ltd. C-384 TTC Industrial Area MIDC Navi Mumbai Pawne District Thane India		
API Lot No.	ACT/01022017		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	10-2017	01-2018	01-2018
Date of Initiation	18-11-2017	08-02-2018	08-02-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms that: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by FDA Mahrashtra India valid till 22-06-2024.

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 07-03-2017 specifying 700g API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Acofide 100mg Tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

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Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group,	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks

		Finished Product Specification		
614.	Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No.E-127,E-128 & 129, North Western Zone, Port Qasim Authority Karachi	Epalrest 50mg Tablet Each Tablet Contains: Epalrestat…50mg (Aldose Reductase Inhibitor) In-house specifications	Form 5-D Dy No. 23708 09-07-2018 PKR. 50,000/- 05-07-2018 Challan # 0775652 As per SRO	Approved by PMDA Firm has submitted copy of GMP certificate issued based on inspection dated 11-08-2020.

Date of submission of stability study data: 24-09-2021

STABILITY STUDY DATA

Manufacturer of API	M/s Symed Labs Limited. Mandollagudem Village, Choutuppal Mandal. Yadadri District, Telangana, India		
API Lot No.	2ER-0360816		
Description of Pack (Container closure system)	Alu-PVC blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	01-2018	01-2018	01-2018
Date of Initiation	07-02-2018	04-06-2018	04-06-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available • Firm has adequate monitoring and controls for stability chambers. Chambers are controlled and monitored through software having alarm system for alerts as well

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm as submitted Copy of GMP Certificate (No.6592/A3/2017) dated 25-04-2017 issued by Drugs Control Administration (Telangana) the certificate specifies that the firm is operating at satisfactory level of GMP compliance.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 15-11-2016 specifying 100g Epalrestat. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Epalrestat tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Decision: Approved with Innovator's specifications.		

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
615.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Amas 7mg Tablet
	Composition	Each Film Coated Tablet Contains: Teriflunomide…7mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16866 dated 07-03-2019 Rs.20,000/- dated 05-03-2019 (0833052)
	Pharmacological Group	Selective Immunosuppressant (ATC L04AA) (Use as medication for multiple sclerosis)
	Form	Form-5
	Finished product Specifications	Innovators specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aubagio by Sanofi Aventis, ANSM
	Me-too status	NA
	GMP status	The firm was inspected on 02-07-2019 and conclusion of inspection was: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remarks of Evaluator [VII]	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 and stability study data as per the requirements of 278th meeting of Registration Board.
	Decision of 312th meeting of Registration Board: Deferred for following: Submission of application on form-5D along with differential fee if applicable, submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	

Date of submission of stability study data: 20-11-2021			
STABILITY STUDY DATA			
Manufacturer of API	M/s Glenmark Life Sciences Ltd. Gujrat India		
API Lot No.	DWD14801		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	TF-02	TF-03	TF-04
Batch Size	200 Tablet	1200 Tablet	700 Tablet
Manufacturing Date	11-2019	12-2019	12-2019
Date of Initiation	30-12-2019	17-12-2019	30-12-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available • Firm has adequate monitoring and controls for stability chambers. Chambers are controlled and monitored through software having alarm system for alerts as well
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm as submitted Copy of GMP Certificate (No.6092154) dated 16-01-2020 issued by Food & Drug Administration (Maharashtra State) India
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-11-2018 specifying 300g Teriflunomide. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Aubagio tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Firm has submitted Form 5D however balance fee is not submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit balance fee since the application is submitted on Form 5D and fee of 20,000 is submitted.**

616.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi

	Brand Name +Dosage Form + Strength	Amas 14 mg Tablet
	Composition	Each Film Coated Tablet Contains: Teriflunomide…14 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16867 dated 07-03-2019 Rs.20,000/- dated 05-03-2019 (0830553)
	Pharmacological Group	Selective Immunosuppressant (ATC L04AA)
	Form	Form-5
	Finished product Specifications	Innovators specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aubagio by Sanofi Aventis, ANSM
	Me-too status	NA
	GMP status	The firm was inspected on 02-07-2019 and conclusion of inspection was: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remarks of Evaluator [VII]	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 and stability study data as per the requirements of 278th meeting of Registration Board.
	Decision of 312th meeting of Registration Board: Deferred for following: Submission of application on form-5D along with differential fee if applicable, submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	

Date of submission of stability study data: Dy.# dated

STABILITY STUDY DATA

Manufacturer of API	M/s Glenmark Life Sciences Ltd. Gujrat India
API Lot No.	DWD14801
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

	Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	TF-02	TF-03	TF-04
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	12-2019	01-2020	01-2020
Date of Initiation	30-12-2019	17-12-2019	30-12-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms: • The HPLC software is 21CFR Compliant. • Audit trail on testing reports is available • Firm has adequate monitoring and controls for stability chambers. Chambers are controlled and monitored through software having alarm system for alerts as well
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm as submitted Copy of GMP Certificate (No.6092154) dated 16-01-2020 issued by Food & Drug Administration (Maharashtra State) India
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-11-2018 specifying 300g Teriflunomide. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study

8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Aubagio tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Firm has submitted Form 5D however balance fee is not submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit balance fee since the application is submitted on Form 5D and fee of 20,000 is submitted.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
617.	M/s Hilton Pharma (Pvt) Ltd Plot No. 13-14, Sector 15, Korangi Industrial Area Karachi	Ferpin 267mg Tablet Each Film Coated Tablet Contains: Pirfenidone…..267mg (Thrombopoeitin receptor agonist) In-house specifications	Form 5D Dy No. 40781 06-12-2018 PKR. 50,000/- 06-12-2018 Duplicate dossier R&I verified	Approved by USFDA

			As per SRO	

Date of submission of stability study data: 11-10-2021

STABILITY STUDY DATA

Manufacturer of API	ZCL Chemicals Limited 3102/B, GIDC Industrial Estate Ankleshwar City District Bharuch Gujrat State India.		
API Lot No.	FEN500520		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	HIL-016-02/21	HIL-036-03/21	HIL-037-04/21
Batch Size	3100 Tablet	3100 Tablet	3100 Tablet
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	10-02-2021	10-02-2021	10-02-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Hilvel Tablet, for which the inspection was conducted on 14-12-2017 and the report was presented in 277th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Audit trail on product testing was available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer

4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by FDA Gujrat State India valid till 06-07-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 17-12-2020 specifying 7.6Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the Mac-Fenid Tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name	Type of Form,	International Availability

		(Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	GMP Inspection Report Date & Remarks
618.	M/s Helix Pharma (Pvt) Ltd Hakimsons house, A/56, SITE Manghopir Road Karachi	Acitan Tablet 10mg Each Film Coated Tablet Contains: Macitentan…..10mg (Antihypertensives for pulmonary arterial hypertension) In-house specifications	Form 5D Dy No. 19548 31-10-2017 PKR. 50,000/- 30-10-2017 Duplicate dossier R&I verified As per SRO	Approved by USFDA

Date of submission of stability study data: 18-06-2021

STABILITY STUDY DATA

Manufacturer of API	Honour Lab Limited Plot No 4, Hetero Infrastructure N. Narsapuram Nakkapalli Mandal Andhra Pradesh India.		
API Lot No.	MC0010916		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	TF001	TF002	TF003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	15-05-2020	15-05-2020	15-05-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Ramelton Tablet, for which the inspection was conducted on 18-08-2017 and the report was presented in 273rd

		meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Audit trail on product testing was available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	~~Firm has submitted stability study data of 3 batches of drug substance as per zone IV A conditions~~
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by DCA Government of Telangana India dated 17-01-2017.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 12-05-2019 specifying 55g API.The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Synjardy tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers	Not submitted

	(real time and accelerated)	

Evaluation by PEC:

- Submit valid GMP certificate of API manufacturer.
- Justify why drug excipient compatibility studies is not performed and your qualitative composition is different from innovator's product.
- Submit API stability study data as per zone IV-A conditions

Decision: Deferred for following submissions:

- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Justification why drug excipient compatibility studies is not performed while the qualitative composition is different from innovator's product.**
- **API stability study data as per zone IV-A conditions.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
619.	M/s Martin Dow Limited Plot No 37, Sector 19, Korangi Industrial Area Karachi.	Jexma 10mg Tablet Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. to Vortioxetine…10mg	Form 5D Dy No. 1007 02-12-2015 PKR 50,000/- 30-11-2015 Duplicate Dossier R&I Verified from R&I section	Trintellix Tablets (**USFDA** Approved) Firm has submitted copy of GMP certificate based on inspection dated 09 09 2022

Date of submission of stability study data: 08-08-2021

STABILITY STUDY DATA

Manufacturer of API	Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China.
API Lot No.	20200610
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH
Time Period	Accelerated: 6 (months)

	Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	NPD-T-1205-L	NPD-T-1275-L	NPD-T-1276-L
Batch Size	5000 Tablets	5000 Tablet	5000 Tablets
Manufacturing Date	11-2020	12-2020	12-2020
Date of Initiation	20-01-2021	20-01-2021	20-01-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Ixaban 5mg Tablets and 10mg Tablet, for which the inspection was conducted on 15-04-2020 and the report was presented in 295th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm • The firm showed the audit trail reports on API and finished product testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (JS20191190) issued by CFDA valid till 29-11-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 18-08-2020 specifying 2.1Kg API. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP

9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Brintellix tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Observation	Response from the firm
1.	Label claim is not as per the reference product	This is with reference to the label claim of applied product as detailed below: Jexma Tablet 10mg Each film coated tablet contains: Vortioxetine …… 10mg 12.71 mg of Vortioxetine hydrobromide is equivalent to 10mg of Vortioxetine. Kindly note that **10mg** Vortioxetine is the required dose which is used in the formulation as mentioned in our Batch Manufacturing Record. However, Each film-coated tablet contains Vortioxetine hydrobromide is equivalent to 10mg vortioxetine as per the Innovator Reference of Brintellix attached in the following pages.

Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
620.	M/s Martin Dow Limited Plot No 37, Sector 19, Korangi Industrial Area Karachi.	Jexma 20mg Tablet Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. to Vortioxetine…20mg	Form 5D Dy No. 1006 02-12-2015 PKR 50,000/- 30-11-2015 Duplicate Dossier R&I Verified from R&I section	Trintellix Tablets (**USFDA** Approved) Firm has submitted copy of GMP certificate based on inspection dated 09 09 2022

Date of submission of stability study data: 08-08-2021

STABILITY STUDY DATA

Manufacturer of API	Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China.		
API Lot No.	20200610		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C/75%±5% RH Real Time: 30˚C ± 2˚C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	NPD-T-1354-L	NPD-T-1393-P	NPD-T-1394-P
Batch Size	5000 Tablets	5000 Tablet	5000 Tablets
Manufacturing Date	02-2021	03-2021	03-2021

Date of Initiation	12-03-2021	12-03-2021	12-03-2021
No. of Batches	03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Ixaban 5mg Tablets and 10mg Tablet, for which the inspection was conducted on 15-04-2020 and the report was presented in 295th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm • The firm showed the audit trail reports on API and finished product testing.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer	
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (JS20191190) issued by CFDA valid till 29-11-2024.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 18-08-2020 specifying 2.1Kg API. The invoice is cleared by AD (I&E) DRAP.	
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study	
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required	
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches	
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Brintellix tablet	

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Observation	Response from the firm
1.	Label claim is not as per the reference product	This is with reference to the label claim of applied product as detailed below: Jexma Tablet 20mg Each film coated tablet contains: Vortioxetine …… 20mg 12.71 mg of Vortioxetine hydrobromide is equivalent to 10mg of Vortioxetine. Kindly note that **20mg** Vortioxetine is the required dose which is used in the formulation as mentioned in our Batch Manufacturing Record. However, Each film-coated tablet contains Vortioxetine hydrobromide is equivalent to 20mg vortioxetine as per the Innovator Reference of Brintellix attached in the following pages.

Decision: Approved with Innovator's specifications.

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

621.	Name and address of manufacture / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan

	Brand Name + Dosage Form and Strength	Glitab Tablet 5mg/500mg
	Composition	Each Film Coated Tablet Contains: Dapagliflozin Popanediol Monohydrate eq to Dapagliflozins .....5mg Metformin HCl..... 500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11407 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	XIGDUO XR (2.5mg/1000mg, 5mg/500mg, 5mg/1000mg, 10mg/500mg, 10mg/1000mg) USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 05-08-2019 and conclusion of inspection was: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remark of the Evaluator [XI]	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm OR submit application on requisite form 5D, stability studies data of three batches as per the guidelines approved in 293rd meeting of Registration Board, along with submission of differential fee. • The reference formulation is film coated extended release tablets and contain immediate release dapagliflozine and extended release metformin hydrochloride drug substance. Revise your formulation and manufacturing outline as per reference formulation along with submission of applicable fee.

Decision of 322nd meeting of Registration Board: Deferred for evaluation of stability study data on its turn

Response by the firm:

Firm has submitted following in the response:

- Application on Form 5-D along with balance fee 55000 dated 12-11-2021
- Revised the formulation label claim as per innovator's product as follows:
  Each film coated bilayer tablet contains:
  Dapagliflozin (as propanediol monohydrate)…….5mg

Metformin HCl (extended release layer).....500mg

- Stability study data of 3 batches

Date of submission of stability study data: Dy.# 31947 dated 22-11-2021

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin Propanediol monohydrate:** M/S Jiangsu Yongan Pharmaceuticals Co., Lt China 18, Provincial Highway 237, Huaian Economic Development Zone, Jiangsu China **Metformin:** Aarti Drugs Pvt Ltd Mahendra Industrial Estate, Ground Floor, Road No. 29, Plot No. 109-D Sion (East) Mumbai India.		
API Lot No.	**Dapagliflozin** Propanediol monohydrate: DGF-20110011 **Metformin:** MEF/19081807		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	354DS01	354DS02	354DS03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	12-09-2020	12-09-2020	12-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	A panel inspection of Sofosbuvir 400 mg tablet conducted on 26th October 2020 and approved in 297 meeting.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate issued by CFDA China valid till 14-01-2024. **Metformin:** Firm has submitted copy of GMP certificate issued by FDA Maharashtra India.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** Firm has submitted copy of commercial invoice cleared dated 04-01-2019 specifying 500g. The invoice is cleared by AD (I&E) DRAP. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 08-11-2019 specifying 1000Kg Metformin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Xigduo tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with following label claim:

Each film coated bilayer tablet contains:
Dapagliflozin (as propanediol monohydrate)…….5mg
Metformin HCl (extended release layer)..... 500mg

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

622.	Name and address of manufacture / Applicant	M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name + Dosage Form and Strength	Levarol inhalation solution 0.63mg
	Composition	Each ml contains: Levalbuterol as HCl..... 0.63mg
	Dairy No. date of R &I fee	Dy. No.229; 02-01-2018; Rs.20,000/- (02-01-2018)
	Pharmacological Group	Beta-2 Agonist
	Type of form	Form 5
	Finished product specifications	U.S.P.
	Pack size and Demand Price	3ml, 5ml, 10ml & as per PRC
	Approval status of product in Reference Regulatory Authorities	Xopenex inhalation solution 0.63mg, 0.021% (3ml) of M/s Oak Pharms Inc. (USFDA Approved)
	Me-too-status	Could not be confirmed
	GMP Status	Last GMP inspection was conducted on 23-07-2018 and report concludes an acceptable level of GMP compliance.
	Remark of the Evaluator [XI]	• Firm has Inhaler section as mentioned in the section approval letter. • Firm has applied three volumes i.e. 3ml, 5ml and 10ml while only 3ml is approved in USFDA. • Stability is required for the applied formulation so firm needs to resubmit the application on Form-5D with submission of additional fees and stability studies data as per decision of 276th meeting.

Decision of 288th meeting of Registration Board: Deferred for following:

- Evidence of approval of required manufacturing facility for 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 and stability study data as per the requirements of 278th meeting of Registration Board.
- Selection of one fill volume only.

Response by the firm:

Firm has only submitted stability study data which is also not as per approved checklist.

Date of submission of stability study data: 25-06-2021

Evaluation by PEC:

- Evidence of approval of required manufacturing facility for 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 and stability study data as per the requirements of 278th meeting of Registration Board.
- Selection of one fill volume only.

- The submitted stability study data is not as per the 14 points checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following submissions:

- **Evidence of approval of required manufacturing facility for 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 balance fee.**
- **Selection of one fill volume only.**
- **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**

623.	Name and address of manufacture / Applicant	M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name + Dosage Form and Strength	Levarol inhalation solution 1.25mg
	Composition	Each ml contains: Levalbuterol as HCl..... 1.25mg
	Dairy No. date of R &I fee	Dy. No.228; 02-01-2018; Rs.20,000/- (02-01-2018)
	Pharmacological Group	Beta-2 Agonist
	Type of form	Form 5
	Finished product specifications	U.S.P.
	Pack size and Demand Price	3ml, 5ml, 10ml & as per PRC
	Approval status of product in Reference Regulatory Authorities	Xopenex inhalation solution 1.25mg, 0.042% (3ml) of M/s Oak Pharms Inc. (USFDA Approved)
	Me-too-status	Could not be confirmed
	GMP Status	Last GMP inspection was conducted on 23-07-2018 and report concludes an acceptable level of GMP compliance.
	Remark of the Evaluator [XI]	• Firm has Inhaler section as mentioned in the section approval letter. • Firm has applied three volumes i.e. 3ml, 5ml and 10ml while only 3ml is approved in USFDA. • Stability is required for the applied formulation so firm needs to resubmit the application on Form-5D with submission of additional fees and stability studies data as per decision of 276th meeting.

Decision of 288th meeting of Registration Board: Deferred for following:

- Evidence of approval of required manufacturing facility for 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 and stability study data as per the requirements of 278th meeting of Registration Board.
- Selection of one fill volume only.

Response by the firm:

Firm has only submitted stability study data which is also not as per approved checklist.

Date of submission of stability study data: 25-06-2021

Evaluation by PEC:

- Evidence of approval of required manufacturing facility for 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 and stability study data as per the requirements of 278th meeting of Registration Board.
- Selection of one fill volume only.
- The submitted stability study data is not as per the 14 points checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following submissions:

- **Evidence of approval of required manufacturing facility for 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 balance fee.**
- **Selection of one fill volume only.**
- **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**

624.	Name and address of manufacture / Applicant	M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name + Dosage Form and Strength	Diacan-M 50/500mg Tablet
	Composition	Each film coated contains: Canagliflozin……50mg Metformin HCl..... 500mg
	Dairy No. date of R &I fee	Dy. No. 332; 22-12-2014 (Duplicate dossier, R&I verified) Rs.50,000/- 22-12-2014
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5D
	Finished product specifications	Inhouse specs
	Pack size and Demand Price	10’s, 20’s, 30’s
	Approval status of product in Reference Regulatory Authorities	Invokamet Tablet (USFDA Approved)
	Me-too-status	CGZin-M Tablet by Helix
	GMP Status	Not submitted

Date of submission of stability study data: 25-11-2021

Evaluation by PEC:

- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.
- The firm has submitted GMP report of inspection conducted on 6-6-23.

Decision: Approved.

The firm will submit stability studies for first three commercial batches.

625.	Name and address of manufacture / Applicant	M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name + Dosage Form and Strength	Diacan-M 50/1000mg Tablet
	Composition	Each film coated contains: Canagliflozin……50mg Metformin HCl..... 1000mg
	Dairy No. date of R &I fee	Dy. No. 333; 22-12-2014 (Duplicate dossier, R&I verified) Rs.50,000/- 22-12-2014
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5D
	Finished product specifications	Inhouse specs
	Pack size and Demand Price	10's, 20's, 30's
	Approval status of product in Reference Regulatory Authorities	Invokamet Tablet (USFDA Approved)
	Me-too-status	CGZin-M Tablet by Helix
	GMP Status	Not submitted

Date of submission of stability study data: 25-11-2021

Evaluation by PEC:

- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.
- The firm has submitted GMP report of inspection conducted on 6-6-23.

Decision: Approved.

The firm will submit stability studies for first three commercial batches.

626.	Name and address of manufacture / Applicant	M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi.

	Brand Name + Dosage Form and Strength	Diacan-M 150/500mg Tablet
	Composition	Each film coated contains: Canagliflozin……150mg Metformin HCl..... 500mg
	Dairy No. date of R &I fee	Dy. No. 334; 22-12-2014 (Duplicate dossier, R&I verified) Rs.50,000/- 22-12-2014
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5D
	Finished product specifications	Inhouse specs
	Pack size and Demand Price	10's, 20's, 30's
	Approval status of product in Reference Regulatory Authorities	Invokamet Tablet (USFDA Approved)
	Me-too-status	CGZin-M Tablet by Helix
	GMP Status	Not submitted
Date of submission of stability study data: 25-11-2021		
Evaluation by PEC:		
• Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd me ting, si the submitted data is scattered and does not contain the information as required in the checklist of 293r meeting Registration Board. • The firm has submitted GMP report of inspection conducted on 6-6-23.		
Decision: Approved. **The firm will submit stability studies for first three commercial batches.**		
627.	Name and address of manufacture / Applicant	M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name + Dosage Form and Strength	Diacan-M 150/1000mg Tablet
	Composition	Each film coated contains: Canagliflozin……150mg Metformin HCl..... 1000mg
	Dairy No. date of R &I fee	Dy. No. 335; 22-12-2014 (Duplicate dossier, R&I verified)

		Rs.50,000/- 22-12-2014
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5D
	Finished product specifications	Inhouse specs
	Pack size and Demand Price	10's, 20's, 30's
	Approval status of product in Reference Regulatory Authorities	Invokamet Tablet (USFDA Approved)
	Me-too-status	CGZin-M Tablet by Helix
	GMP Status	Not submitted
Date of submission of stability study data: 25-11-2021		
Evaluation by PEC:		

- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd me ting, si the submitted data is scattered and does not contain the information as required in the checklist of 293r meeting Registration Board.
- The firm has submitted GMP report of inspection conducted on 6-6-23.

Decision: Approved.

The firm will submit stability studies for first three commercial batches.

628.	Name and address of manufacture / Applicant	M/s High-Q Pharmaceuticals, Plot No.224/23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Myrdron 25mg Prolonged release tablet
	Composition	Each prolonged Release Tablet contains: Mirabegron 25mg
	Dairy No. date of R &I fee	Dy. No 1487 dated 14-10-2016; Rs. 50,000/- dated 13-10-2016. Duplicate File Bearing Dy. No.1863 dated 13-07-2021.
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of form	Form 5-D
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	BETMIGA mirabegron 25 mg film-coated prolonged release tablet, TGA approved.
	Me-too-status	Mibega Tablets 25mg, Getz Pharma, Reg. No. 089375

	GMP Status	GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Remark of the Evaluator [XI]	• Firm was communicated that master formulation for the applied formulation does not depict any ingredient for prolong release of the active. Master formulation needs revision along with applicable fee. • They replied that Methocel K100 is used as an extended release agent in master formulation. However, no Methocel K100 has been used in master formulation. • Stability studies data as per requirement determined in 293rd meeting of Registration Board is required.

Decision of 316th meeting of Registration Board: Deferred for the following;

- Revision of master formulation for inclusion of excipient for prolonged release profile.
- Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

Response by the firm:

Firm has submitted stability study data along with revision of master formulation and submitted 7500 fee for revision of inactive ingredients.

Date of submission of stability study data: 27-05-2021and again submitted on 17-03-2022

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co. Ltd. China		
API Lot No.	20180204V		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	2MIPD01/20	2MIPD02/20	2MIPD03/20
Batch Size	6333 3Tablets	6333 3Tablets	6333 3Tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	25-09-2020	25-09-2020	25-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to their previous onsite investigation investigation for vesoft tablet for which inspection was conducted on 12-07-2018 and the report confirms 21 CFR compliant HPLC system along with audit trail reports
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License No. GAN 20160125 valid till 26-11-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 17-07-2018 specifying 1Kg. Theinvoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has submitted drug excipient compatibility studies
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Myrbetric tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Decision: Approved with Innovator's specifications.

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

629.	Name and address of manufacture / Applicant	M/s High-Q Pharmaceuticals, Plot No.224/23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Myrdron 50mg Prolonged Release Tablet
	Composition	Each prolonged release tablet contains: Mirabegron 50mg
	Dairy No. date of R &I fee	Dy. No 1484 dated 14-10-2016; Rs. 50,000/- dated 13-10-2016. Duplicate File Bearing Dy. No.1862 dated 13-07-2021.
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of form	Form 5-D
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	BETMIGA mirabegron 50 mg film-coated prolonged release tablet, TGA approved.
	Me-too-status	Mibega Tablets 50mg, Getz Pharma, Reg. No. 089375
	GMP Status	GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Remark of the Evaluator [XI]	• Firm was communicated that master formulation for the applied formulation does not depict any ingredient for prolong release of the active. Master formulation needs revision along with applicable fee. • They replied that Methocel K100 is used as an extended release agent in master formulation. However, no Methocel K100 has been used in master formulation. • Stability studies data as per requirement determined in 293rd meeting of Registration Board is required.

Decision of 316th meeting of Registration Board: Deferred for the following;

- Revision of master formulation for inclusion of excipient for prolonged release profile.
- Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

Response by the firm:

Firm has submitted stability study data along with revision of master formulation and submitted 7500 fee for revision of inactive ingredients.

Date of submission of stability study data: 27-05-2021and again submitted on 17-03-2022

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co. Ltd. China		
API Lot No.	20180204V		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	5MlPD01/20	5MlPD02/20	5MlPD03/20
Batch Size	3166 3Tablets	3166 3Tablets	3166 3Tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	30-09-2020	30-09-2020	30-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to their previous onsite investigation investigation for vesoft tablet for which inspection was conducted on 12-07-2018 and the report confirms 21 CFR compliant HPLC system along with audit trail reports
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License No. GAN 20160125 valid till 26-11-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 17-07-2018 specifying 1Kg. Theinvoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has submitted drug excipient compatibility studies
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Myrbetric tablet
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with Innovator's specifications.

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

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
630.	M/s Horizon Healthcare (Pvt) Ltd.	Empazin Plus SR 25/1000mg Tablet	Form 5 Dy No. 10675 05-03-2019	Approved by USFDA

	Plot No.35-A, Small Industrial Estate, Taxila,	Each Film Coated Tablet Contains: Empagliflozin…25mg Metformin HCl…1000mg (Anti-diabetic) In-house specifications	PKR. 20,000/- 05-03-2019 As per SRO	

Date of submission of stability study data: 18-06-2021

Evaluation by PEC:

- Revision of master formulation as per the innovator's product along with submission of requisite fee.
- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.

Decision: Deferred for following submissions:

- **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**
- **Revision of master formulation as per the innovator's product along with submission of requisite fee.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
631.	M/s Searle Pakistan Limited, F-319, SITE, Karachi.	Peditral Low Liquid (Regular Flavour) 500ml Each 500ml Contains: Sodium chloride……1.3gm Trisodium citrate dehydrate….1.45gm Potassium Chloride……0.75gm Dextrose anhydrous..... 6.75gm (Oral electrolytes) In-house specifications	Form 5 Dy No. 1072 22-06-2012 PKR. 8,000/- 21-06-2012 As per SRO Duplicate Dossier R&I verified	Approved by USFDA Firm has submitted cGMP certificate issued on the basis of inspection conducted on 19-07-2022.

Date of submission of stability study data: 08-06-2021

Evaluation by PEC:

- Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting.
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
- Evidence of requisite manufacturing facility required to manufacture the applied product.
- Submit evidence of submission of complete applicable fee of registration, since only 8000 fee submission is provided.
- The 8000 fee is submitted by Searle Pakistan Limited, 1st Floor, N.I.C Building Abbasi Shaheed road Off Shahrah e Faisal Karachi, while the applicant firm is Searle Pakistan Limited, F-319, SITE, Karachi. Clarification is required in this regard.
- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.

Decision: Deferred for following submissions:

- **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting.**
- **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5D along with balance fee.**
- **Evidence of requisite manufacturing facility required to manufacture the applied product.**
- **Evidence of submission of complete applicable fee of registration, since only 8000 fee submission is provided.**
- **Clarification since the 8000 fee is submitted by Searle Pakistan Limited, 1st Floor, N.I.C Building Abbasi Shaheed road Off Shahrah e Faisal Karachi, while the applicant firm is Searle Pakistan Limited, F-319, SITE, Karachi.**
- **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
632.	M/s Searle Pakistan Limited, F-319, SITE, Karachi.	Peditral Low Liquid (Orange Flavour) 500ml Each 500ml Contains: Sodium chloride……1.3gm Trisodium citrate dehydrate….1.45gm Potassium Chloride……0.75gm Dextrose anhydrous..... 6.75gm (Oral electrolytes) In-house specifications	Form 5 Dy No. 1073 22-06-2012 PKR. 8,000/- 21-06-2012 As per SRO Duplicate Dossier R&I verified	Approved by USFDA Firm has submitted cGMP certificate issued on the basis of inspection conducted on 19-07-2022.

Date of submission of stability study data: 08-06-2021

Evaluation by PEC:

- Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting.
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
- Evidence of requisite manufacturing facility required to manufacture the applied product.
- Submit evidence of submission of complete applicable fee of registration, since only 8000 fee submission is provided.
- The 8000 fee is submitted by Searle Pakistan Limited, 1st Floor, N.I.C Building Abbasi Shaheed road Off Shahrah e Faisal Karachi, while the applicant firm is Searle Pakistan Limited, F-319, SITE, Karachi. Clarification is required in this regard.
- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.

Decision: Deferred for following submissions:

- **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting.**
- **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5D along with balance fee.**
- **Evidence of requisite manufacturing facility required to manufacture the applied product.**
- **Evidence of submission of complete applicable fee of registration, since only 8000 fee submission is provided.**

- **Clarification since the 8000 fee is submitted by Searle Pakistan Limited, 1st Floor, N.I.C Building Abbasi Shaheed road Off Shahrah e Faisal Karachi, while the applicant firm is Searle Pakistan Limited, F-319, SITE, Karachi.**
- **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
633.	M/s Searle Pakistan Limited, F-319, SITE, Karachi.	Peditral Low Liquid (Bubble Gum Flavour) 500ml Each 500ml Contains: Sodium chloride……1.3gm Trisodium citrate dehydrate….1.45gm Potassium Chloride……0.75gm Dextrose anhydrous..... 6.75gm (Oral electrolytes) In-house specifications	Form 5 Dy No. 1074 22-06-2012 PKR. 8,000/- 21-06-2012 As per SRO Duplicate Dossier R&I verified	Approved by USFDA Firm has submitted cGMP certificate issued on the basis of inspection conducted on 19-07-2022.

Date of submission of stability study data: 08-06-2021

Evaluation by PEC:

- Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting.
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
- Evidence of requisite manufacturing facility required to manufacture the applied product.
- Submit evidence of submission of complete applicable fee of registration, since only 8000 fee submission is provided.
- The 8000 fee is submitted by Searle Pakistan Limited, 1st Floor, N.I.C Building Abbasi Shaheed road Off Shahrah e Faisal Karachi, while the applicant firm is Searle Pakistan Limited, F-319, SITE, Karachi. Clarification is required in this regard.
- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.

Decision: Deferred for following submissions:

- **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Board in its 275th meeting.**
- **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5D along with balance fee.**
- **Evidence of requisite manufacturing facility required to manufacture the applied product.**
- **Evidence of submission of complete applicable fee of registration, since only 8000 fee submission is provided.**
- **Clarification since the 8000 fee is submitted by Searle Pakistan Limited, 1st Floor, N.I.C Building Abbasi Shaheed road Off Shahrah e Faisal Karachi, while the applicant firm is Searle Pakistan Limited, F-319, SITE, Karachi.**
- **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**

634.	Name and address of manufacturer/ Applicant	M/s Hudson Pharma (Pvt.) Ltd., D-93, North Western Industrial Zone, Port Qasim Authority, Karachi (Eye/Ear & Nasal drops general section (revised).
	Brand Name + Dosage Form + Strength	Brimson S 0.1% Eye Drops.
	Composition	Each ml Contains: Brimonidine Tartrate 1mg
	Diary No. Date of R & I & fee	Dy. No 10114 dated 04-03-2019; Rs.50,000/- 04-03-2019.
	Pharmacological Group	Antiglaucoma Preparations and Miotic.
	Type of Form.	Form-5D.
	Finished product Specification.	Manufacturer specifications.
	Pack size & Demanded Price	5ml, 15ml & as per SRO.
	Approval status of product in Reference Regulatory Authorities.	ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1%, USFDA approved.
	Me-too status.	Could not be confirmed.
	GMP status.	Same as above.
	Remarks of the Evaluator PEC-XIII	• Master formulation is not provided. • Complete method of manufacturing along with sterilization procedure is required. • Stability study data as per the guidelines provided in 293rd meeting of Registration Board is required.

Decision of 307th meeting of Registration Board: Deferred for following:

- Master formulation.
- Complete method of manufacturing along with sterilization procedure.
- Stability study data as per the guidelines provided in 293rd meeting of Registration Board.

Response by the firm:

Firm has only submitted stability study data of 3 batches of the product on 27-04-2021. However, following are still deficient

- Master formulation
- Complete method of manufacturing along with sterilization procedure.
- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.

Decision: Deferred for following submissions:

- **Complete Master formulation**
- **Complete method of manufacturing along with sterilization procedure.**
- **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**

635.	Name and address of manufacture / Applicant	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Ulprate 5mg Tablet
	Composition	Each Uncoated Tablet Contains: Ulipristal Acetate…5mg
	Dairy No. date of R &I fee	Dy.No 14561 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Other sex hormones and modulators of the genital system
	Type of form	Form 5
	Finished product specifications	The firm has claimed manufacturer‘s specifications.

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ulipristal Acetate 5 mg tablets (MHRA) Approved
	Me-too-status	Could not be confirmed
	GMP Status	Firm has submitted copy of GMP certificate issued based on inspection dated 03-04-2023.
Date of submission of stability study data: 04-05-2021		
Evaluation: • Evidence of already registered product by DRAP / me-too status or else application on Form 5D along with balance fee. • Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP. • Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.		
Decision: Deferred for following submissions: • **Evidence of already registered product by DRAP / me-too status or else application on Form 5D along with balance fee.** • **Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP.** • **Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.**		
636.	Name and address of manufacture / Applicant	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Emzon-M 5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Dairy No. date of R &I fee	Dy.No 14545 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form 5
	Finished product specifications	The firm has claimed manufacturer‘s specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	EMA Approved
	Me-too-status	Diampa M Tablets by Getz
	GMP Status	Firm has submitted copy of GMP certificate issued based on inspection dated 03-04-2023.

Date of submission of stability study data: 22-12-2021
Evaluation: • Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.
Decision: Deferred for submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.

Case No. 03 Registration applications of CTD cases

a. Contract manufacturing applications as per Decision of 173rd meeting of Authority

637.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Shawan Pharma issued on the basis of inspection dated 24-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Shawan pharma dated 03-09-2019 specifying Dry powder injection (Cephalosporin) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8329: 27-03-2023
	Details of fee submitted	PKR 75,000/-: 28-11-2022
	The proposed proprietary name / brand name	**Axon 500mg Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmaceutical form of applied drug	Almost white to off white colored powder filled in glass vial.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Oxidil Injection by Sami
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against Rovitrox Injection by Valor Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% RH Accelerated: 40˚C ± 2˚C / 25% RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Real Time: 0, 1, 3, 6 (Months) Accelerated: 0, 1, 3, 6 (Months)		
Batch No.	098	099	100
Batch Size	10100 Vials	10100 Vials	10100 Vials
Manufacturing Date	02-2016	02-2016	02-2016
Date of Initiation	10-03-2016	07-03-2016	13-03-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 09-02-2021 specifying import of 20Kg ceftriaxone. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
3.	Submit COA of relevant batch of API from the API manufacturer.	
4.	Justify the use of 5ml WFI as diluent since the innovator's product has recommended different volume of diluent.	
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	
6.	Submit compatibility studies with the recommended diluent.	
7.	Submit complete analytical method of the drug product	
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	
9.	Submit in-use stability studies report	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Clarify regarding the stability initiation date of each batch since different date is mentioned in stability summary sheet and raw data sheets	
12.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	

13.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision: Registration Board was apprised that the same formulation manufactured by M/s Shawan Pharmaceuticals, Rawalpindi was considered by the Board in its 331st meeting and was deferred for above cited observations. The manufacturer firm has replied to those shortcomings and those cases are also presented in the instant meeting.

Therefore, based on the response of the firm in deferred case, the Board decided to approve the product.

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter and the submission of following;

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall select one route of administration whether IM or IV.**
- **Firm shall submit pharmaceutical equivalence against the innovator / reference product before issuance of Registraton letter.**

638.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Shawan Pharma issued on the basis of inspection dated 24-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Shawan pharma dated 03-09-2019 specifying Dry powder injection (Cephalosporin) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8330: 27-03-2023

	Details of fee submitted	PKR 75,000/-: 29-11-2022
	The proposed proprietary name / brand name	**Axon 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone as Sodium…..1g
	Pharmaceutical form of applied drug	Almost white to off white colored powder filled in glass vial.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Oxidil Injection by Sami
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against Rovitrox Injection by Valor Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% RH Accelerated: 40˚C ± 2˚C / 25% RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Real Time: 0, 1, 3, 6 (Months) Accelerated: 0, 1, 3, 6 (Months)		
Batch No.	136	137	138
Batch Size	10100 Vials	10100 Vials	10100 Vials
Manufacturing Date	02-2016	02-2016	02-2016
Date of Initiation	10-03-2016	07-03-2016	13-03-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 09-02-2021 specifying import of 20Kg ceftriaxone. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
3.	Submit COA of relevant batch of API from the API manufacturer.	
4.	Justify the use of 5ml WFI as diluent since the innovator's product has recommended different volume of diluent.	
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	
6.	Submit compatibility studies with the recommended diluent.	
7.	Submit complete analytical method of the drug product	
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	
9.	Submit in-use stability studies report	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Clarify regarding the stability initiation date of each batch since different date is mentioned in stability summary sheet and raw data sheets	

12.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
13.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision: Registration Board was apprised that the same formulation manufactured by M/s Shawan Pharmaceuticals, Rawalpindi was considered by the Board in its 331st meeting and was deferred for above cited observations. The manufacturer firm has replied to those shortcomings and those cases are also presented in the instant meeting.

Therefore, based on the response of the firm in deferred case, the Board decided to approve the product.

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter and the submission of following;

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall select one route of administration whether IM or IV.**
- **Firm shall submit pharmaceutical equivalence against the innovator / reference product before issuance of Registraton letter.**

639.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cortex Pharmaceuticals. Plot # 16-A, SS-4, RCCI, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Shawan Pharma issued on the basis of inspection dated 24-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Shawan pharma dated 03-09-2019 specifying Dry powder injection (Cephalosporin) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7693: 17-03-2023
	Details of fee submitted	PKR 75,000/-: 02-12-2021
	The proposed proprietary name / brand name	**Efodux 1000mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone as Sodium…..1g
	Pharmaceutical form of applied drug	Almost white to off white colored powder filled in glass vial.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Oxidil Injection by Sami
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

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

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30°C ± 2°C / 35% RH Accelerated: 40°C ± 2°C / 25% RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Real Time: 0, 1, 3, 6 (Months) Accelerated: 0, 1, 3, 6 (Months)		
Batch No.	136	137	138
Batch Size	10100 Vials	10100 Vials	10100 Vials
Manufacturing Date	02-2016	02-2016	02-2016
Date of Initiation	10-03-2016	07-03-2016	13-03-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023..

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 09-02-2021 specifying import of 20Kg ceftriaxone. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
3.	Submit COA of relevant batch of API from the API manufacturer.	
4.	Justify the use of 5ml WFI as diluent since the innovator's product has recommended different volume of diluent.	
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	
6.	Submit compatibility studies with the recommended diluent.	
7.	Submit complete analytical method of the drug product	
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	
9.	Submit in-use stability studies report	

10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Clarify regarding the stability initiation date of each batch since different date is mentioned in stability summary sheet and raw data sheets	
12.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
13.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision: Registration Board was apprised that the same formulation manufactured by M/s Shawan Pharmaceuticals, Rawalpindi was considered by the Board in its 331st meeting and was deferred for above cited observations. The manufacturer firm has replied to those shortcomings and those cases are also presented in the instant meeting.

Therefore, based on the response of the firm in deferred case, the Board decided to approve the product.

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter and the submission of following;

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall select one route of administration whether IM or IV.**
- **Firm shall submit pharmaceutical equivalence against the innovator / reference product before issuance of Registraton letter.**

640.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on theinspection dated 23-04-2019. The certificate is valid till 22-04-2022.

		The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on theinspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29331: 17-10-2022
	Details of fee submitted	PKR 75,000/-: 26-08-2022
	The proposed proprietary name / brand name	**Nextphen 10mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule Contains: Nalbuphine HCl……10mg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml **(USFDA** Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri

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

STABILITY STUDY DATA

Manufacturer of API	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
API Lot No.	
Description of Pack (Container closure system)	Glass ampoule
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	A-429	A-552	A-608
Batch Size	15000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	04-2018	01-2019	04-2019
Date of Initiation	28-05-2018	06-02-2019	24-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-01-2020 specifying import of 0.05Kg nalbuphine hydrochloride. The invoice is **not** attested by AD (I&E) DRAP Field office. Firm has also submitted copy of Form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The product development and stability study data of the contract manufacturer was considered by Registration Board in its 323rd meeting and deferred for submission of following documents:

- Submit contract manufacturing agreement between contract giver and contract acceptor.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Submit data of batch analysis of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture"* since the submitted COA is for

the batch manufactured in December 2020 while the drug product batches were manufactured in 2018 and 2019.

- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify your master formulation without any solvent / diluent, further justify how you are using sodium chloride as solvent.
- Justify your master formulation which is significantly different from the innovator product in terms of quantitative composition where you have used sodium citrate, sodium chloride and citric acid anhydrous in 29.71%, 6.34% and 36.03% respectively, since the innovator product specifies sodium citrate, sodium chloride and citric acid anhydrous in 0.94%, 0.2% and 1.26% respectively.
- Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify how you are not performing terminal sterilization for your product.
- Specify the container closure system whether available in amber color glass ampoule or otherwise.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain complete tests as recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify the pH of your product between 3 to 4.5 since the pH of the innovator product is 3.5 to 3.7. Revise your specifications along with submission of requisite fee.
- Justify your analytical method for assay testing of the drug product which is based on UV analysis, since the analytical method of drug substance manufacturer as well as innovator / reference product is based on HPLC method.
- Justify your validation studies of the drug product in the light of ICH guidelines, since your analysis and reporting of the results is not exactly in line with the ICH recommendations.
- Justify why the stability study data of three different batches is submitted from those for which batch analysis is provided in section 3.2.P.5.4.
- You have submitted that the drug substance manufacturer is Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri, but the drug substance used in the manufacturing of 3 batches of drug product is from any other source. Justification is required in this regard.
- Justify significant difference in the batch size of your products ranging from 15,000 to 50,000 ampoules. Justify your response in the light of the minimum and maximum capacity of your manufacturing equipments.
- Justify the pH of batch A-608 where the pH value exceed 3.70 to 3.78 during stability studies, since the maximum pH limit defined by innovator product is 3.70.
- Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. Submit complete data with proper separators and in a sequence along with raw data sheets.
- Submit reference of previous approval of applications with stability study data of the firm instead of mentioning not applicable.
- Submit valid GMP certificate of the drug substance manufacturer.
- Submit documents for the procurement of API with approval from DRAP for the relevant batch of API which is used in the manufacturing of stability batches.
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.
- Submit copy of batch manufacturing record of 3 stability batches.

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

641.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad.
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Saffron Pharma dated 12-11-2020 based on the inspection dated 11-11-2020.
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 470: 05-01-2023
	Details of fee submitted	PKR 75,000/-: 21-12-2022
	The proposed proprietary name / brand name	**Metason 50mcg Nasal Spray**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Spray Contains: Mometasone Furoate…50mcg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Decongestant and other nasal preparations for topical use.
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not submitted
	For generic drugs (me-too status)	Nasomet Aqueous Nasal Spray by Sante
	Name and address of API manufacturer.	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

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

STABILITY STUDY DATA

Manufacturer of API	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.		
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			

Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of resuisite manufacturing facility approval by Licensing Division, DRAP and Central Licensing Board.	
2.	Submit complete label claim in section 1.5.2 as per the recommendations laid down in CTD guidance document along with submission of requisite fee.	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9 as per the recommendations laid down in CTD guidance document instead of submitting SmPC of a product without specifying the regulatory authority which has approved that product.	
4.	The label claim submitted in the proposed label design in section 1.5.11 i.e. "Each Spray Contains: Mometasone Furoate…50mcg" is non scientific and does not provide the actual information.	

5.	Submit information is section 1.6.5 as per the CTD guidance document since you have only submitted GMP certificate of API manufacturer in that section.		

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

642.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3146: 02-02-2023
	Details of fee submitted	PKR 75,000/- : 09-01-2023
	The proposed proprietary name / brand name	**Ampica 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Ampicillin (as trihydrate) 500mg
	Pharmaceutical form of applied drug	Gray opaque cap and light blue opaque body hard gelatin capsule

	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Penbritin Capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Penbritin Capsule of GSK. Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Penbritin Capsule of GSK.

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

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00002/012/2022		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-01	A-02	A-03
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:		
• Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer. • Provide verification studies of drug substance from drug product manufacturer. • Specify whether the drug substance used is in compacted form or micronized. • Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided. • Submit evidence of automatic analyzer equipped with spectrophotometer having analysis capability at 480 nm. • Provide COA of reference standard / working standard actually used in the analysis of drug product. • Provide description of container closure system whether Alu-Alu blister or otherwise. • USP monograph specifies Iodometric Assay specified in USP general chapter <425> while in stability studies and analytical method verification you have used HPLC method for assay testing. Clarification is required in this regard. • Justify how the dissolution testing performed in stability studies is according to the method specified in USP monograph. • Submit copy of invoice for procurement of drug substance from Pharmagen. • Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
643.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3145: 02-02-2023
	Details of fee submitted	PKR 75,000/- : 09-01-2023
	The proposed proprietary name / brand name	**Ampica 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Ampicillin (as trihydrate) 250mg
	Pharmaceutical form of applied drug	White to yellowish color powder in the suspension bottle
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Ampcigen suspension by Genera
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against ampicillin suspension without specifying the name of manufacturer or brand name.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00002/012/2022		
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-04	A-05	A-06
Batch Size	120 Bottles	120 Bottles	120 Bottles
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.

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

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Specify whether the drug substance used is in compacted form or micronized.
- Justify why the qualitative composition is different from that of the innovator's product.
- Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence studies have been performed.
- Justify why pharmaceutical equivalence studies are not performed against innovator / reference product.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since FDA dissolution method have recommended dissolution parameters for the applied product.
- Provide preservative effectiveness studies for the drug product in section 3.2.P.2.5.
- Provide compatibility studies of the product along with recommended diluent in section 3.2.P.2.6.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Provide details of the container closure system of the applied product whether packed in glass bottle or PET bottle along with the color of the bottle.
- Justify how 120 bottles batch size is sufficient enough to complete the stability studies.
- USP monograph specifies Iodometric Assay specified in USP general chapter <425> while in stability studies and analytical method verification you have used HPLC method for assay testing. Clarification is required in this regard.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

644.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3144: 02-02-2023
	Details of fee submitted	PKR 75,000/- : 09-01-2023
	The proposed proprietary name / brand name	**Amoxace 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Amoxicillin (as trihydrate) 500mg
	Pharmaceutical form of applied drug	Blue opaque cap and pink opaque body hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Amoxil Capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Amoxil Capsule of GSK. Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Amoxil Capsule of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	000130/0047/2022
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-01	A-02	A-03
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	22-02-2022	22-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided.
- Justify why microbial enumeration test is not performed at the batch analysis and batch release stage as evident from the batch release certificate provided in section 3.2.P.5.4.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

• Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
645.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3143: 02-02-2023
	Details of fee submitted	PKR 75,000/- : 09-01-2023
	The proposed proprietary name / brand name	**Amoxace 125mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Amoxicillin (as trihydrate) 125mg
	Pharmaceutical form of applied drug	White to yellowish color powder in the suspension bottle
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic

	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Amoxil suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Amoxil suspension of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	000130/0047/2022		
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-04	A-05	A-06
Batch Size	120 Bottles	120 Bottles	120 Bottles
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	22-02-2022	22-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.

- Provide verification studies of drug substance from drug product manufacturer.
- Justify the use of amoxicillin trihydrate compacted API for manufacturing of suspension, since the reference product reveals that micronized particle size is required to achieve the desired drug contents after reconstitution.
- Justify why the qualitative composition is different from that of the innovator's product.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since FDA dissolution method have recommended dissolution parameters for the applied product.
- Provide preservative effectiveness studies for the drug product in section 3.2.P.2.5.
- Provide compatibility studies of the product along with recommended diluent in section 3.2.P.2.6.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Provide details of the container closure system of the applied product whether packed in glass bottle or PET bottle along with the color of the bottle.
- Justify how 120 bottles batch size is sufficient enough to complete the stability studies.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

646.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Daneen Pharma (Pvt.) Ltd. Pakistan 27-Sundar Industrial Estate Sundar, Raiwind rd, Sundar Industrial Estate, Lahore, Punjab.
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi. Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-10-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 30-10-2019 which specifies Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 24069 dated 01-09-2021
	Details of fee submitted	PKR 75,000/- Dated 10-08-2021

	The proposed proprietary name / brand name	**Erglif 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Ertugliflozin L-Pyroglutamic acid is eq. to Ertugliflozin… 5mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Pharmaceutical form of applied drug	Pink color, Pentagonal, film coated, biconvex tablet, plain from both sides.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	STEGLATRO (Merck & Co. Inc, USA) approved by USFDA.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

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

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China
API Lot No.	ETG20180901
Description of Pack (Container closure system)	Alu-alu Blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-235-01	19SB-236-02	19SB-237-03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	06-01-2020	06-01-2020	06-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No.JS20180935) issued by CFDA China. The certificate is valid till 26-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 02-10-2018 specifying 500.2g of Ertugliflozin L-Pyroglutamic acid. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application		
647.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Daneen Pharma (Pvt.) Ltd. Pakistan 27-Sundar Industrial Estate Sundar, Raiwind rd, Sundar Industrial Estate, Lahore, Punjab.
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi. Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-10-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 30-10-2019 which specifies Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 23856 dated 31-08-2021
	Details of fee submitted	PKR 75,000/- Dated 10-08-2021
	The proposed proprietary name / brand name	**Erglif 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid is eq. to Ertugliflozin…. 15mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Pharmaceutical form of applied drug	Red color, oblong, film coated tablet, engraved "GENIX" on one side and score line on other side.
	Reference to Finished product specifications	Innovator's

	Proposed Pack size	7's, 10's, 14's, 20's, 28's, & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	STEGLATRO (Merck & Co. Inc, USA) approved by USFDA.
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,

		justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Steglatro Tablet 15mg manufactured by Merck sharp & Dohme (MSD). Firm has submitted CDP results of their product against the innovator's product Steglatro Tablet 15mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China		
API Lot No.	ETG20180901		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-241-01	19SB-242-02	19SB-243-03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	07-01-2020	07-01-2020	07-01-2020

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No.JS20180935) issued by CFDA China. The certificate is valid till 26-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 02-10-2018 specifying 500.2g of Ertugliflozin L-Pyroglutamic acid. The invoice is cleared by AD (I&E) DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan. **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

648.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver)
	GMP status of the firm	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020 specifying Dry Vial Injection section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24630 dated 31-08-2022
	Details of fee submitted	PKR 75,000/- Dated 06-06-2022
	The proposed proprietary name / brand name	**Wincef 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium…500mg Sulbactam as Sodium…500mg
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(PMDA Japan Approved)
	For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Sulzone injection of Biocare
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.		
API Lot No.	2027BJ81NE		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	520	529	530

Batch Size	5700 vials	5700 vials	5700 vials
Manufacturing Date	01-2023	02-2023	02-2023
Date of Initiation	23-01-2023	08-03-2023	08-03-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate specifying import of 200Kg Cefoperazone sodium-Sulbactam sodium dated 11-08-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Firm has initially submitted application for contract manufacturing from M/s Cure Laboratories Islamabad, however later on the firm vide its letter dated 30-11-2023 has request to change the contract manufacturer to M/s Nicholas Pharmaceuticals, Islamabad. Firm has also submitted data from the new contract manufacturer along with submission of 75000 fee for change of contract manufacturer.

Decision: Approved with Innovator's specifications in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

649.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver)
	GMP status of the firm	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Nicholas Pharmaceuticals on the basis of inspection conducted on 28-01-2020 specifying Dry Vial Injection section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24631 dated 31-08-2022
	Details of fee submitted	PKR 75,000/- Dated 06-06-2022
	The proposed proprietary name / brand name	**Wincef 2gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(PMDA Japan Approved)
	For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Sulzone injection of Biocare
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.		
API Lot No.	2027BJ81NE		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	528	551	564

Batch Size	7100 vials	7100 vials	7100 vials
Manufacturing Date	02-2023	03-2023	04-2023
Date of Initiation	08-03-2023	08-03-2023	10-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate specifying import of 200Kg Cefoperazone sodium-Sulbactam sodium dated 11-08-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

- Firm has initially submitted application for contract manufacturing from M/s Cure Laboratories Islamabad, however later on the firm vide its letter dated 30-11-2023 has request to change the contract manufacturer to M/s Nicholas Pharmaceuticals, Islamabad. Firm has also submitted data from the new contract manufacturer along with submission of 75000 fee for change of contract manufacturer.

Decision: Approved with Innovator's specifications in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application

b. Deferred cases of local manufacturing

650.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Filix Pharmaceuticals Pvt Ltd. 4-A, Main Road, RCCI, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Shawan Pharma issued on the basis of inspection dated 24-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Shawan pharma dated 03-09-2019 specifying Dry powder injection (Cephalosporin) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11037: 06-05-2022
	Details of fee submitted	PKR 75,000/-: 14-09-2021
	The proposed proprietary name / brand name	**Everzone 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmaceutical form of applied drug	Almost white to off white colored powder filled in glass vial.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Oxidil Injection by Sami
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against Rovitrox Injection by Valor Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
API Lot No.	
Description of Pack	Glass vials

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% RH Accelerated: 40˚C ± 2˚C / 25% RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Real Time: 0, 1, 3, 6 (Months) Accelerated: 0, 1, 3, 6 (Months)		
Batch No.	098	099	100
Batch Size	10100 Vials	10100 Vials	10100 Vials
Manufacturing Date	02-2016	02-2016	02-2016
Date of Initiation	10-03-2016	07-03-2016	13-03-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 09-02-2021 specifying import of 20Kg ceftriaxone. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
3.	Submit COA of relevant batch of API from the API manufacturer.	
4.	Justify the use of 5ml WFI as diluent since the innovator's product has recommended different volume of diluent.	
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	
6.	Submit compatibility studies with the recommended diluent.	
7.	Submit complete analytical method of the drug product	
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	
9.	Submit in-use stability studies report	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Clarify regarding the stability initiation date of each batch since different date is mentioned in stability summary sheet and raw data sheets	
12.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
13.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 331st meeting of Registration Board:

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

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submittd by the firm
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Submittd by the firm
3.	Submit COA of relevant batch of API from the API manufacturer.	COA for Lot No. 011507041 is submitted
4.	Justify the use of 5ml WFI as diluent since the innovator's product has recommended different volume of diluent.	Quantity of WFI is corrected as per innovator's product
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	Firm has submitted pharmaceutical equivalence against rovitrox injection of valor pharma
6.	Submit compatibility studies with the recommended diluent.	Submittd by the firm
7.	Submit complete analytical method of the drug product	Submittd by the firm
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	Submittd by the firm
9.	Submit in-use stability studies report	Submittd by the firm
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Submittd by the firm
11.	Clarify regarding the stability initiation date of each batch since different date is mentioned in stability summary sheet and raw data sheets	Submittd by the firm
12.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submittd by the firm
13.	Documents for the procurement of API with approval from DRAP (in case of import).	Submittd by the firm

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan

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

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter and the submission of following documents;

- **Firm shall select one route of administration whether IM or IV.**
- **Firm shall submit pharmaceutical equivalence against the innovator / reference product before issuance of Registraton letter.**

651.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Filix Pharmaceuticals Pvt Ltd. 4-A, Main Road, RCCI, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Shawan Pharma issued on the basis of inspection dated 24-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Shawan pharma dated 03-09-2019 specifying Dry powder injection (Cephalosporin) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13242: 31-05-2022
	Details of fee submitted	PKR 75,000/-: 14-09-2021
	The proposed proprietary name / brand name	**Everzone 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone as Sodium…..1g

	Pharmaceutical form of applied drug	Almost white to off white colored powder filled in glass vial.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Oxidil Injection by Sami
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against Rovitrox Injection by Valor Pharma.

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

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% RH Accelerated: 40˚C ± 2˚C / 25% RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Real Time: 0, 1, 3, 6 (Months) Accelerated: 0, 1, 3, 6 (Months)		
Batch No.	136	137	138
Batch Size	10100 Vials	10100 Vials	10100 Vials
Manufacturing Date	02-2016	02-2016	02-2016
Date of Initiation	10-03-2016	07-03-2016	13-03-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 09-02-2021 specifying import of 20Kg ceftriaxone. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of stability testing of 3 batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
3.	Submit COA of relevant batch of API from the API manufacturer.	
4.	Justify the use of 5ml WFI as diluent since the innovator's product has recommended different volume of diluent.	
5.	Justify why pharmaceutical equivalence studiesare not conducted against the innovator / reference product.	
6.	Submit compatibility studies with the recommended diluent.	
7.	Submit complete analytical method of the drug product	
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	
9.	Submit in-use stability studies report	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Clarify regarding the stability initiation date of each batch since different date is mentioned in stability summary sheet and raw data sheets	
12.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
13.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 331st meeting of Registration Board:

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

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submittd by the firm
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Submittd by the firm
3.	Submit COA of relevant batch of API from the API manufacturer.	COA for Lot No. 011507041 is submitted
4.	Justify the use of 5ml WFI as diluent since the innovator's product has recommended different volume of diluent.	Quantity of WFI is corrected as per innovator's product
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	Firm has submitted pharmaceutical equivalence against rovitrox injection of valor pharma
6.	Submit compatibility studies with the recommended diluent.	Submittd by the firm
7.	Submit complete analytical method of the drug product	Submittd by the firm
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	Submittd by the firm
9.	Submit in-use stability studies report	Submittd by the firm
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Submittd by the firm
11.	Clarify regarding the stability initiation date of each batch since different date is mentioned in stability summary sheet and raw data sheets	Submittd by the firm
12.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submittd by the firm

13.	Documents for the procurement of API with approval from DRAP (in case of import).	Submittd by the firm

Decision: Approved in the light of legal opinion of the member registration board representing the Division of Law and Justice, Government of Pakistan

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

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter and the submission of following documents;

- **Firm shall select one route of administration whether IM or IV.**
- **Firm shall submit pharmaceutical equivalence against the innovator / reference product before issuance of Registraton letter.**

652.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 24-02-2021.
	GMP status of the firm	Firm has submitted copy of inspection report of M/s EG Pharmaceuticals dated 13-02-2019 recommending the renewal of DML.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000752) dated 29-08-2012 specifying dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20656: 29-07-2021
	Details of fee submitted	PKR 50,000/-: 02-03-2021
	The proposed proprietary name / brand name	**NAGZONE 250mg Injection IM**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Oxidil 250mg Injection IM.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	Q011910019		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	402	463	821
Batch Size	5,000 vials	6,000 vials	5,000 vials
Manufacturing Date	02-2020	03-2020	10-2018
Date of Initiation	05-02-2020	12-03-2020	25-10-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous product specific inspection of the firm has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:	
Shortcomings communicated	**Response by the firm**
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has not submitted any differential fee.
Specify whether your application is for IV or IM use.	The application is for IM use
Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from EG Pharmaceuticals. **However, the specifications are different from that of USP monograph.**
Justify your analytical method verification studies for the drug substance in which chromatographic conditions including column specifications, injection volume and flow rate is different from that specified in USP monograph.	Firm has submitted analytical method verification studies. **However the method verification studies are not as per ICH and USP recommendations and the analytical method in verification studies is different from that mentioned in section 3.2.S.4.2.**
Submit COA of relevant batch of drug substance in section 3.2.S.4.4 which is actually used for manufacturing of three stability batches since the lot number of drug substance specified in BMRs are 0220-657R, 1018-232R, 1119-574R.	Firm has submitted COA of batch number Q011910019. **As per the submitted COA the manufacturing date of the drug substance is October 2019. While Batch No. 821 was manufactured on 25-10-2018.**
Submit COA of reference standard / working standard actually used in the analysis of drug substance and drug product.	**Not submitted by the firm**
Specify the batch number, expiry date and manufacturer of Rocephin 250mg injection against which pharmaceutical equivalence studies are performed since this product is not registered in Pakistan.	Firm has now submitted Oxidil 250mg IM Injection Batch No. 047G mfg date 12/2020
Justify the compatibility study of your product, since the reconstitution diluent is lignocaine while in section 3.2.P.2.6 you have specified water for injection.	Reconstitution diluent Lidocaine HCl is fully compatible in FPP. Diluent is same as recommended by innovator. **However the reconstitution studies data is not provided.**

Justify why the specifications of drug product submitted in section 3.2.P.5.1 does not include complete tests as specified in USP monograph.	Firm has submitted specifications of drug product **which are still not as per USP in assay test.**
Justify why the analytical procedures of the drug product is different from that of USP monograph.	**No justification submitted by the firm**
Justify how three commercial batches were released in the market without performing complete tests as per USP monograph.	Firm has submitted batch release report of three batches **in which complete tests as per USP monograph are still not performed.**
Justify why sterility test and water determination is not performed during stability studies.	We performed these tests after one year from batch manufacturing.
Justify how only 1 HPLC chromatogram of standard solution and 1 chromatogram of sample solution is used to determine assay of the commercial batch of the drug product.	**No justification submitted by the firm**
Submit data in section 3.2.P.8.3 as per the checklist provided in CTD guidance document approved by the Registration Board so that further evaluation could be carried out.	Only stability data sheets is provided **complete data as per 6 point checklist is still not submitted.**

Decision of 316th meeting: Deferred for following:

- Submission of differential fee of Rs. 25,000, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Scientific justification for having the drug substance specification different from that of USP monograph.
- Scientific justification for manufacturing of Batch No. 821 on 25-10-2018 using drug substance batch number Q011910019 which is manufactured in October 2019.
- Submission of COA of reference standard / working standard actually used in the analysis of drug substance and drug product.
- Submission of compatibility studies of the drug product with the recommended diluent.
- Scientific justification for having drug product specifications different from that of USP monograph.
- Scientific justification why the analytical procedures of the drug product is different from that of USP monograph.
- Scientific justification how three commercial batches were released in the market without performing complete tests as per USP monograph.
- Scientific justification how only 1 HPLC chromatogram of standard solution and 1 chromatogram of sample solution is used to determine assay of the commercial batch of the drug product.
- Submission of complete data in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Firm's reply: Firm has submitted following:

- Drug substance specifications as per USP monograph.
- COA of drug substance from M/s Sinopharm Weqeida of batch no. 2081704066 declaring that previous COA was submitted inadvertently.
- COA of working standard form M/s Sinopharm Weqeida.
- Revised drug product specifications and analytical procedure as per USP monograph of "Ceftriaxone for injection" without requisite fee for pre-approval change/correction in drug product specifications.

• Firm has referred to the performance of system suitability for the use of 1 standard and sample solution value for Assay calculation solution. • Stability studies data as per 6 points of guidance document (PE&R/GL/AF/004) approved by the Registration Board.		
Decision: Approved • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
653.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 24-02-2021.
	GMP status of the firm	Firm has submitted copy of inspection report of M/s EG Pharmaceuticals dated 13-02-2019 recommending the renewal of DML.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000752) dated 29-08-2012 specifying dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20657: 29-07-2021
	Details of fee submitted	PKR 50,000/-: 02-03-2021
	The proposed proprietary name / brand name	**NAGZONE 500mg Injection IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……500mg

	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 500mg Injection IM.

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

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	Q011910019		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	297	444	856
Batch Size	7,000 vials	8,000 vials	6,000 vials
Manufacturing Date	10-2019	03-2020	11-2018
Date of Initiation	28-10-2019	06-03-2020	22-11-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous product specific inspection of the firm has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has not submitted any differential fee.
Specify whether your application is for IV or IM use.	The application is for IM use
Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from EG Pharmaceuticals. **However, the specifications are different from that of USP monograph.**
Justify your analytical method verification studies for the drug substance in which chromatographic conditions including column specifications, injection volume and flow rate is different from that specified in USP monograph.	Firm has submitted analytical method verification studies. **However the method verification studies are not as per ICH and SP recommendations and the analytical method in verification studies is different from that mentioned in section 3.2.S.4.2.**
Submit COA of relevant batch of drug substance in section 3.2.S.4.4 which is actually used for manufacturing of three stability batches since the lot number of drug substance specified in BMRs are 0220-657R, 1018-232R, 1119-574R.	Firm has submitted COA of batch number Q011910019. **As per the submitted COA the manufacturing date of the drug substance is October 2019. While Batch No. 856 was manufactured on 22-11-2018.**
Submit COA of reference standard / working standard actually used in the analysis of drug substance and drug product.	**Not submitted by the firm**
Specify the batch number, expiry date and manufacturer of Rocephin 250mg injection against which pharmaceutical equivalence studies are performed since this product is not registered in Pakistan.	Firm has now submitted Rocephin 500mg IM Injection Batch No. B0065 mfg date 06/2020
Justify the compatibility study of your product, since the reconstitution diluent is lignocaine while in section 3.2.P.2.6 you have specified water for injection.	Reconstitution diluent Lidocaine HCl is fully compatible in FPP. Diluent is same as recommended by innovator. **However the reconstitution studies data is not provided.**

Justify why the specifications of drug product submitted in section 3.2.P.5.1 does not include complete tests as specified in USP monograph.	Firm has submitted specifications of drug product **which are still not as per USP in assay test.**
Justify why the analytical procedures of the drug product is different from that of USP monograph.	**No justification submitted by the firm**
Justify how three commercial batches were released in the market without performing complete tests as per USP monograph.	Firm has submitted batch release report of three batches **in which complete tests as per USP monograph are still not performed.**
Justify why sterility test and water determination is not performed during stability studies.	We performed these tests after one year from batch manufacturing.
Justify how only 1 HPLC chromatogram of standard solution and 1 chromatogram of sample solution is used to determine assay of the commercial batch of the drug product.	**No justification submitted by the firm**
Submit data in section 3.2.P.8.3 as per the checklist provided in CTD guidance document approved by the Registration Board so that further evaluation could be carried out.	Only stability data sheets is provided **complete data as per 6 point checklist is still not submitted.**

Decision: Deferred for following:

- Submission of differential fee of Rs. 25,000, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Scientific justification for having the drug substance specification different from that of USP monograph.
- Scientific justification for manufacturing of Batch No. 856 on 21-11-2018 using drug substance batch number Q011910019 which is manufactured in October 2019.
- Submission of COA of reference standard / working standard actually used in the analysis of drug substance and drug product.
- Submission of compatibility studies of the drug product with the recommended diluent.
- Scientific justification for having drug product specifications different from that of USP monograph.
- Scientific justification why the analytical procedures of the drug product is different from that of USP monograph.
- Scientific justification how three commercial batches were released in the market without performing complete tests as per USP monograph.
- Scientific justification how only 1 HPLC chromatogram of standard solution and 1 chromatogram of sample solution is used to determine assay of the commercial batch of the drug product.
- Submission of complete data in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Firm's reply: Firm has submitted following:

- Drug substance specifications as per USP monograph.
- COA of drug substance from M/s Sinopharm Weqeida of batch no. 2081704066 declaring that previous COA was submitted inadvertently.
- COA of working standard form M/s Sinopharm Weqeida.
- Revised drug product specifications and analytical procedure as per USP monograph of "Ceftriaxone for injection" without requisite fee for pre-approval change/correction in drug product specifications.

• Firm has referred to the performance of system suitability for the use of 1 standard and sample solution value for Assay calculation solution. • Stability studies data as per 6 points of guidance document (PE&R/GL/AF/004) approved by the Registration Board.		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
654.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 24-02-2021.
	GMP status of the firm	Firm has submitted copy of inspection report of M/s EG Pharmaceuticals dated 13-02-2019 recommending the renewal of DML.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000752) dated 29-08-2012 specifying dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20658: 29-07-2021
	Details of fee submitted	PKR 50,000/-: 02-03-2021
	The proposed proprietary name / brand name	**NAGZONE 1g Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……1g

	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 1g Injection.

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

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	Q011910019		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	386	290	504
Batch Size	7,000 vials	4,000 vials	7,000 vials
Manufacturing Date	10-2020	10-2019	04-2020
Date of Initiation	23-01-2020	31-10-2019	07-04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous product specific inspection of the firm has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has not submitted any differential fee.
Specify whether your application is for IV or IM use.	The application is for IV use
Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from EG Pharmaceuticals. **However, the specifications are different from that of USP monograph.**
Justify your analytical method verification studies for the drug substance in which chromatographic conditions including column specifications, injection volume and flow rate is different from that specified in USP monograph.	Firm has submitted analytical method verification studies. **However the method verification studies are not as per ICH and SP recommendations and the analytical method in verification studies is different from that mentioned in section 3.2.S.4.2.**
Submit COA of relevant batch of drug substance in section 3.2.S.4.4 which is actually used for manufacturing of three stability batches since the lot number of drug substance specified in BMRs are 0220-657R, 1018-232R, 1119-574R.	Firm has submitted COA of batch number Q011910019.
Submit COA of reference standard / working standard actually used in the analysis of drug substance and drug product.	**Not submitted by the firm**
Specify the batch number, expiry date and manufacturer of Rocephin 250mg injection against which pharmaceutical equivalence studies are performed since this product is not registered in Pakistan.	Firm has now submitted Rocephin 1g IV Injection Batch No. B0784 mfg date 06/2020
Justify the compatibility study of your product, since the reconstitution diluent is lignocaine while in section 3.2.P.2.6 you have specified water for injection.	Reconstitution diluent WFI is fully compatible in FPP. Diluent is same as recommended by innovator. **However the reconstitution studies data is not provided.**
Justify why the specifications of drug product submitted in section 3.2.P.5.1 does not include complete tests as specified in USP monograph.	Firm has submitted specifications of drug product **which are still not as per USP in assay test.**

Justify why the analytical procedures of the drug product is different from that of USP monograph.	**No justification submitted by the firm**
Justify how three commercial batches were released in the market without performing complete tests as per USP monograph.	Firm has submitted batch release report of three batches **in which complete tests as per USP monograph are still not performed.**
Justify why sterility test and water determination is not performed during stability studies.	We performed these tests after one year from batch manufacturing.
Justify how only 1 HPLC chromatogram of standard solution and 1 chromatogram of sample solution is used to determine assay of the commercial batch of the drug product.	**No justification submitted by the firm**
Submit data in section 3.2.P.8.3 as per the checklist provided in CTD guidance document approved by the Registration Board so that further evaluation could be carried out.	Only stability data sheets is provided **complete data as per 6 point checklist is still not submitted.**

Decision: Deferred for following:

- Submission of differential fee of Rs. 25,000, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Scientific justification for having the drug substance specification different from that of USP monograph.
- Submission of COA of reference standard / working standard actually used in the analysis of drug substance and drug product.
- Submission of compatibility studies of the drug product with the recommended diluent.
- Scientific justification for having drug product specifications different from that of USP monograph.
- Scientific justification why the analytical procedures of the drug product is different from that of USP monograph.
- Scientific justification how three commercial batches were released in the market without performing complete tests as per USP monograph.
- Scientific justification how only 1 HPLC chromatogram of standard solution and 1 chromatogram of sample solution is used to determine assay of the commercial batch of the drug product.
- Submission of complete data in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Firm's reply: Firm has submitted following:

- Drug substance specifications as per USP monograph.
- COA of drug substance from M/s Sinopharm Weqeida of batch no. 2081704066 declaring that previous COA was submitted inadvertently.
- COA of working standard form M/s Sinopharm Weqeida.
- Revised drug product specifications and analytical procedure as per USP monograph of "Ceftriaxone for injection" without requisite fee for pre-approval change/correction in drug product specifications.
- Firm has referred to the performance of system suitability for the use of 1 standard and sample solution value for Assay calculation solution.
- Stability studies data as per 6 points of guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
655.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29104: 13-10-2022
	Details of fee submitted	PKR 75,000/-: 03-10-2022
	The proposed proprietary name / brand name	**Lotinon Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Solution Contains: Tobramycin……3mg Loteprednol Etabonate…….5mg
	Pharmaceutical form of applied drug	Ophthalmic Solution

	Pharmacotherapeutic Group of (API)	Antibiotic and corticosteroid
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zylet ophthalmic suspension (**USFDA** Approved)
	For generic drugs (me-too status)	Lotepred-T Ophthalmic Suspension by Sante
	Name and address of API manufacturer.	**Loteprednol:** Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India. **Tobramycin:** Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Loteprednol:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. **Tobramycin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability

		data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Lotepred-D eye drops of Sante.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Loteprednol:** Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India. **Tobramycin:** Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
API Lot No.	**Loteprednol:** **Tobramycin:** TB2007011
Description of Pack (Container closure system)	LDPE Bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	174E	202E	209E
Batch Size			
Manufacturing Date	02-2020	06-2020	09-2020
Date of Initiation	04-02-2020	01-07-2020	10-09-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Loteprednol:** **Tobramycin:** Firm has submitted copy of GMP certificate (No. GD20190944) issued by CFDA China. The certificate was valid till 31-01-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	You have applied for ophthalmic solution while the applied product is approved as ophthalmic suspension in USFDA. Correct the applied formulation along with submission of full fee of registration.	
2.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer	

	as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
3.	Submit verification studies of the analytical method of Tobramycin drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
4.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	
5.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	
6.	Submit specifications and analytical procedures of the Loteprednol drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
7.	Submit verification studies of the analytical method of Loteprednol drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
8.	Submit COA of relevant batch of Loteprednol API from both API manufacturer as well as drug product manufacturer.	
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	
10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	
11.	Provide preservative effectiveness studies.	
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	
13.	Provide analytical method of drug product in section 3.2.P.5.2	
14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not	

	specify batch size, API lot number and various other required information.	
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	
18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	

Decision of 331st meeting of Registration Board:

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

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	You have applied for ophthalmic solution while the applied product is approved as ophthalmic suspension in USFDA. Correct the applied formulation along with submission of full fee of registration.	Revised form 5F is submitted
2.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
3.	Submit verification studies of the analytical method of Tobramycin drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
4.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	Revised specifications submitted
5.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted

6.	Submit specifications and analytical procedures of the Loteprednol drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
7.	Submit verification studies of the analytical method of Loteprednol drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
8.	Submit COA of relevant batch of Loteprednol API from both API manufacturer as well as drug product manufacturer.	Submitted
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	Submitted
10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non availability of innovator product we have performed PE studies with brand leader
11.	Provide preservative effectiveness studies.	Submitted
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	Revised specifications submitted
13.	Provide analytical method of drug product in section 3.2.P.5.2	Submitted
14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	Submitted
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	Submitted
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	New stability chamber for semi permeable container is to be purchased
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet	Submitted

	and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	
18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	Submitted

Decision: Approved with following label claim:

Each ml of ophthalmic suspension Contains:

Tobramycin……3mg

Loteprednol Etabonate…….5mg

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

656.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29103: 13-10-2022
	Details of fee submitted	PKR 75,000/-: 03-10-2022
	The proposed proprietary name / brand name	**Tobton-D Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Suspension Contains: Tobramycin……3mg Dexamethasone…….1mg
	Pharmaceutical form of applied drug	Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Antibiotic and steroid
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tobradex ophthalmic suspension (**USFDA** Approved)
	For generic drugs (me-too status)	Bracin-D Ophthalmic Suspension by Atco Lab
	Name and address of API manufacturer.	**Dexamethasone:** Zhejiang Xianju Pharmaceutical Co. Ltd No. 1, Xian Yao Road Xianju, Zhejiang China. **Tobramycin:** Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Dexamethasone:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 9 months. **Tobramycin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Bracin-D eye drops of Atco Lab
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		
Manufacturer of API	**Dexamethasone:** Zhejiang Xianju Pharmaceutical Co. Ltd No. 1, Xian Yao Road Xianju, Zhejiang China.	

	Tobramycin: Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.		
API Lot No.	**Dexamethasone:** **Tobramycin:** TB2007011		
Description of Pack (Container closure system)	LDPE Bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	228E	229E	250E
Batch Size			
Manufacturing Date	12-2020	12-2020	03-2021
Date of Initiation	10-12-2020	14-12-2020	30-04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dexamethasone:** **Tobramycin:** Firm has submitted copy of GMP certificate (No. GD20190944) issued by CFDA China. The certificate was valid till 31-01-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of Tobramycin drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
3.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	
4.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	
5.	Submit specifications and analytical procedures of the Dexamethasone drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
6.	Submit verification studies of the analytical method of Dexamethasone drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
7.	Submit COA of relevant batch of Dexamethasone APi from both API manufacturer as well as drug product manufacturer.	
8.	Submit Dexamthasone API stability study data till the shelf life since real time stability data is submitted till 9 months only.	
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	

10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	
11.	Provide preservative effectiveness studies.	
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	
13.	Justify why the assay method is different from that specified in USP monograph in terms of column specifications and calculation formula.	
14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	
18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	

Decision of 331st meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer	Submitted

	as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of Tobramycin drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
3.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	Revised specifications submitted
4.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted
5.	Submit specifications and analytical procedures of the Dexamethasone drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
6.	Submit verification studies of the analytical method of Dexamethasone drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
7.	Submit COA of relevant batch of Dexamethasone APi from both API manufacturer as well as drug product manufacturer.	Submitted
8.	Submit Dexamthasone API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	Submitted
10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non availability of reference product PE studies was conducted with brand leader
11.	Provide preservative effectiveness studies.	Submitted
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	Revised specifications submitted
13.	Justify why the assay method is different from that specified in USP monograph in terms of column specifications and calculation formula.	Revised specifications submitted
14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy	Submitted

	study is not as per the target concentration specified in analytical method.	
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	Submitted
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	New stability chamber for semi permeable is to be purchased
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	Submitted
18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	Submitted

Decision: Approved.

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

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

657.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29102: 13-10-2022
	Details of fee submitted	PKR 75,000/-: 03-10-2022
	The proposed proprietary name / brand name	**Nepton 1mg Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of suspension Contains: Nepafenac…..1mg
	Pharmaceutical form of applied drug	Yellowish green slightly viscous suspension filled in LDPE bottle.
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nevanac ophthalmic suspension USFDA Approved)
	For generic drugs (me-too status)	Nepanac Ophathalmic Suspension by Remington Pharma
	Name and address of API manufacturer.	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its

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

STABILITY STUDY DATA	
Manufacturer of API	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
API Lot No.	3051805046
Description of Pack	LDPE Bottle

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	232E	233E	238E
Batch Size			
Manufacturing Date	12-2020	12-2020	01-2021
Date of Initiation	07-01-2021	09-2020	01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6097475) issued by FDA Maharashtra State India. The certificate was valid till 12-01-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 26-02-2020 specifying import of 500g Nepafenac micronized and sterilized. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	As per submitted Form 5-F, the name of applicant is Winthrox Laboratories and the name of manufacturer is Welmed Pharmaceutical. Correct the Form 5-F along with submission of requisite fee.	
2.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
3.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from both drug substance as well as drug product manufacturer.	
5.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	
6.	Provide preservative effectiveness studies.	
7.	The analytical method for pharmaceutical equivalence specifies UV method while analytical record of HPLC testing is submitted. Clarify.	
8.	Provide specifications of drug product in section 3.2.P.5.1	
9.	Justify why the product specifications do not include a test for the assay of preservative contents.	
10.	Provide analytical method of drug product in section 3.2.P.5.2	
11.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	
12.	Justify the broad and assymetric peaks in validation studies. Furthermore, you have not determined peak parameters like theoretical plates and tailing factor.	
13	Justify the adaptation of a wide pH range i.e. 6.7 – 7.6 since the desired pH value is 7.4 and results of all batches is also above 7.4.	
14.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD	

	guidance document since your data sheets does not specify batch size, API lot number and various other required information.		
15.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.		
16.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.		
15.	Justify the consistent peak tailing in your stability chromatograms.		
16.	Submit valid GMP certificate of the drug substance manufacturer, since the submitted certificate was valid till 12-01-2022.		

Decision of 331st meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	As per submitted Form 5-F, the name of applicant is Winthrox Laboratories and the name of manufacturer is Welmed Pharmaceutical. Correct the Form 5-F along with submission of requisite fee.	Revised Form 5F has been submitted
2.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
3.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
4.	Submit COA of relevant batch of API from both drug substance as well as drug product manufacturer.	Submitted
5.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non availability of reference product we have performed PE studies against brand leader
6.	Provide preservative effectiveness studies.	Submitted

7.	The analytical method for pharmaceutical equivalence specifies UV method while analytical record of HPLC testing is submitted. Clarify.	Revised method and studies are submitted
8.	Provide specifications of drug product in section 3.2.P.5.1	Submitted
9.	Justify why the product specifications do not include a test for the assay of preservative contents.	Revised specifications submitted
10.	Provide analytical method of drug product in section 3.2.P.5.2	Submitted
11.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	Revised report with correction is submitted
12.	Justify the broad and assymetric peaks in validation studies. Furthermore, you have not determined peak parameters like theoretical plates and tailing factor.	Revised validation report is submitted
13	Justify the adaptation of a wide pH range i.e. 6.7 – 7.6 since the desired pH value is 7.4 and results of all batches is also above 7.4.	pH limit has been revised
14.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	Submitted
15.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	New stability chamber for semi permeable container is to be purchased
16.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	Submitted
15.	Justify the consistent peak tailing in your stability chromatograms.	Tailing factor is less than 2 that's why our peaks are consistent.

16.	Submit valid GMP certificate of the drug substance manufacturer, since the submitted certificate was valid till 12-01-2022.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 30,000/- for correction in the name and address of applicant firm as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

658.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmed Pharmaceutical Industries (Pvt) Ltd. 108-R-2, Industrial Estate, Gadoon Swabi.**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12617: 24-05-2022
	Details of fee submitted	PKR 75,000/-: 14-12-2021
	The proposed proprietary name / brand name	**MEDLONE-T 5mg+3mg Ophthalmic Solution**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Solution Contains: Tobramycin……3mg Loteprednol Etabonate…….5mg
	Pharmaceutical form of applied drug	Ophthalmic Solution
	Pharmacotherapeutic Group of (API)	Antibiotic and corticosteroid
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zylet ophthalmic suspension (**USFDA** Approved)
	For generic drugs (me-too status)	Lotepred-T Ophthalmic Suspension by Sante
	Name and address of API manufacturer.	**Loteprednol:** Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India. **Tobramycin:** Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	**Loteprednol:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability

	(Conditions & duration of Stability studies)	data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. **Tobramycin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Lotepred-D eye drops of Sante.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Loteprednol:** Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India. **Tobramycin:** Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
API Lot No.	**Loteprednol:** **Tobramycin:** TB2007011
Description of Pack (Container closure system)	LDPE Bottle
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	174E	202E	209E
Batch Size			
Manufacturing Date	02-2020	06-2020	09-2020
Date of Initiation	04-02-2020	01-07-2020	10-09-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Loteprednol:** **Tobramycin:** Firm has submitted copy of GMP certificate (No. GD20190944) issued by CFDA China. The certificate was valid till 31-01-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	You have applied for ophthalmic solution while the applied product is approved as ophthalmic suspension in USFDA. Correct the applied	

	formulation along with submission of full fee of registration.	
2.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
3.	Submit verification studies of the analytical method of Tobramycin drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
4.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	
5.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	
6.	Submit specifications and analytical procedures of the Loteprednol drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
7.	Submit verification studies of the analytical method of Loteprednol drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
8.	Submit COA of relevant batch of Loteprednol API from both API manufacturer as well as drug product manufacturer.	
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	
10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	
11.	Provide preservative effectiveness studies.	
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	
13.	Provide analytical method of drug product in section 3.2.P.5.2	

14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	
18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	

Decision of 331st meeting of Registration Board:

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

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	You have applied for ophthalmic solution while the applied product is approved as ophthalmic suspension in USFDA. Correct the applied formulation along with submission of full fee of registration.	Revised form 5F is submitted
2.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
3.	Submit verification studies of the analytical method of Tobramycin drug substance	Submitted

	performed by drug product manufacturer in section 3.2.S.4.3.	
4.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	Revised specifications submitted
5.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted
6.	Submit specifications and analytical procedures of the Loteprednol drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
7.	Submit verification studies of the analytical method of Loteprednol drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
8.	Submit COA of relevant batch of Loteprednol API from both API manufacturer as well as drug product manufacturer.	Submitted
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	Submitted
10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non availability of innovator product we have performed PE studies with brand leader
11.	Provide preservative effectiveness studies.	Submitted
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	Revised specifications submitted
13.	Provide analytical method of drug product in section 3.2.P.5.2	Submitted
14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	Submitted
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your	Submitted

	data sheets does not specify batch size, API lot number and various other required information.	
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	New stability chamber for semi permeable container is to be purchased
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	Submitted
18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	Submitted

Decision: Approved with following label claim:

Each ml of ophthalmic suspension Contains:

Tobramycin……3mg

Loteprednol Etabonate…….5mg

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

659.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmed Pharmaceutical Industries (Pvt) Ltd. 108-R-2, Industrial Estate, Gadoon Swabi.**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12638: 24-05-2022
	Details of fee submitted	PKR 75,000/-: 14-12-2021
	The proposed proprietary name / brand name	**TYCIN-D 1mg+3mg Ophthalmic Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Suspension Contains: Tobramycin……3mg Dexamethasone…….1mg
	Pharmaceutical form of applied drug	Ophthalmic Suspension
	Pharmacotherapeutic Group of (API)	Antibiotic and steroid
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tobradex ophthalmic suspension (**USFDA** Approved)
	For generic drugs (me-too status)	Bracin-D Ophthalmic Suspension by Atco Lab
	Name and address of API manufacturer.	**Dexamethasone:** Zhejiang Xianju Pharmaceutical Co. Ltd No. 1, Xian Yao Road Xianju, Zhejiang China. **Tobramycin:** Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road,

		Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Dexamethasone:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 9 months. **Tobramycin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Bracin-D eye drops of Atco Lab

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

STABILITY STUDY DATA			
Manufacturer of API	**Dexamethasone:** Zhejiang Xianju Pharmaceutical Co. Ltd No. 1, Xian Yao Road Xianju, Zhejiang China. **Tobramycin:** Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.		
API Lot No.	**Dexamethasone:** **Tobramycin:** TB2007011		
Description of Pack (Container closure system)	LDPE Bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	228E	229E	250E
Batch Size			
Manufacturing Date	12-2020	12-2020	03-2021
Date of Initiation	10-12-2020	14-12-2020	30-04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dexamethasone:** **Tobramycin:** Firm has submitted copy of GMP certificate (No. GD20190944) issued by CFDA China. The certificate was valid till 31-01-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of Tobramycin drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
3.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	
4.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	
5.	Submit specifications and analytical procedures of the Dexamethasone drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
6.	Submit verification studies of the analytical method of Dexamethasone drug substance performed by drug product manufacturer in section 3.2.S.4.3.	

7.	Submit COA of relevant batch of Dexamethasone APi from both API manufacturer as well as drug product manufacturer.	
8.	Submit Dexamthasone API stability study data till the shelf life since real time stability data is submitted till 9 months only.	
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	
10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	
11.	Provide preservative effectiveness studies.	
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	
13.	Justify why the assay method is different from that specified in USP monograph in terms of column specifications and calculation formula.	
14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	

18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	

Decision of 331st meeting of Registration Board:

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

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the Tobramycin drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
2.	Submit verification studies of the analytical method of Tobramycin drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
3.	The assay limit of Tobramycin specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	Revised specifications submitted
4.	Submit Tobramycin API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted
5.	Submit specifications and analytical procedures of the Dexamethasone drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
6.	Submit verification studies of the analytical method of Dexamethasone drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
7.	Submit COA of relevant batch of Dexamethasone APi from both API manufacturer as well as drug product manufacturer.	Submitted
8.	Submit Dexamthasone API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted
9.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	Submitted

10.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non availability of reference product we have performed PE studies with brand leader
11.	Provide preservative effectiveness studies.	Submitted
12.	Justify why the product specifications do not include a test for the assay of preservative contents.	Revised specifications submitted
13.	Justify why the assay method is different from that specified in USP monograph in terms of column specifications and calculation formula.	Revised assay method has been submitted
14.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	Submitted
15.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	Submitted
16.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	New stability chamber for semi permeable is to be purchased
17.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	Submitted
18.	Submit GMP certificate and evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	Submitted

Decision: Approved

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

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

660.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmed Pharmaceutical Industries (Pvt) Ltd. 108-R-2, Industrial Estate, Gadoon Swabi.**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11825: 16-05-2022
	Details of fee submitted	PKR 75,000/-: 14-12-2021
	The proposed proprietary name / brand name	**TYCIN 3mg Ophthalmic solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Solution Contains: Tobramycin…3mg
	Pharmaceutical form of applied drug	Ophthalmic solution
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Tobrex ophthalmic solution (**USFDA** Approved)
	For generic drugs (me-too status)	Tobnove Sterile Ophthalmic Solution by Novex Pharma
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product

		against the comparator i.e. Eyebrex 3mg/ml eye drops of Barrett Hodgson
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province China.		
API Lot No.	TB2007011		
Description of Pack (Container closure system)	LDPE Bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	215E	234E	235E
Batch Size			
Manufacturing Date	09-2020	01-2021	01-2021
Date of Initiation	10-09-2020	10-01-2021	10-01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20190944) issued by CFDA China. The certificate was valid till 31-01-2024.

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
3.	The assay limit specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	
4.	Submit API stability study data till the shelf life since real time stability data is submitted till 9 months only.	
5.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	
6.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	
7.	Provide preservative effectiveness studies.	
8.	Justify why the product specifications do not include a test for the assay of preservative contents.	
9.	Justify why the assay calculation formula is different from that specified in USP monograph.	
10.	Provide complete report of validation studies of the analytical method of drug product since you have	

	submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	
11.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	
12.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	
13.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	
14.	Submit evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	

Decision of 331st meeting of Registration Board:

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

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
2.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
3.	The assay limit specified by drug substance manufacturer is ≥900 ug/ml while you have defined the assay limit as 98.5% to 101.5%. Justify how drug product manufacturer can change the assay limits.	Revised specifications submitted
4.	Submit API stability study data till the shelf life since real time stability data is submitted till 9 months only.	Submitted

5.	Provide drug-excipient compatibility studies since the qualitative composition is different from the innovator's product.	Submitted
6.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non availability of reference product PE studies was conducted with brand leader
7.	Provide preservative effectiveness studies.	Submitted
8.	Justify why the product specifications do not include a test for the assay of preservative contents.	Revised specifications submitted
9.	Justify why the assay calculation formula is different from that specified in USP monograph.	Revised method is submitted
10.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	Submitted
11.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	Submitted
12.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	New stability chamber for impermeable to be purchased
13.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	Submitted
14.	Submit evidence of procurement of drug substance including ADC attested invoice / clearane certificate.	Submitted

Decision: Approved.

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

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

661.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmed Pharmaceutical Industries (Pvt) Ltd. 108-R-2, Industrial Estate, Gadoon Swabi.**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories (Pvt) Ltd. Plot No. K-219/A, Phase-II SITE Super Highway Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Winthrox Laboratories dated 17-12-2020 based on the inspection dated 19-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License of M/s Winthrox Laboratories dated 08-06-2021. The letter specifies sterile eye drop (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12637: 24-05-2022
	Details of fee submitted	PKR 75,000/-: 14-12-2021
	The proposed proprietary name / brand name	**NEFMED Ophthalmic suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of suspension Contains: Nepafenac…..1mg
	Pharmaceutical form of applied drug	Yellowish green slightly viscous suspension filled in LDPE bottle.
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Nevanac ophthalmic suspension USFDA Approved)
	For generic drugs (me-too status)	Nepanac Ophathalmic Suspension by Remington Pharma
	Name and address of API manufacturer.	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Nepanac eye drops of Remington pharma

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

STABILITY STUDY DATA

Manufacturer of API	Flax Laboratories, Plot No. B-29/1, MIDC Mahad Village Birwadi Mahad District Raigad Maharashtra India.		
API Lot No.			
Description of Pack (Container closure system)	LDPE Bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	232E	233E	238E
Batch Size			
Manufacturing Date	12-2020	12-2020	01-2021
Date of Initiation	07-01-2021	09-2020	01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6097475) issued by FDA Maharashtra State India. The certificate was valid till 12-01-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 26-02-2020 specifying import of 500g Nepafenac micronized and sterilized. The invoice is cleared by AD (I&E) DRAP.

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	As per submitted Form 5-F, the name of applicant is Winthrox Laboratories and the name of manufacturer is Welmed Pharmaceutical. Correct the Form 5-F along with submission of requisite fee.	
2.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
3.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from both drug substance as well as drug product manufacturer.	
5.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	
6.	Provide preservative effectiveness studies.	
7.	The analytical method for pharmaceutical equivalence specifies UV method while analytical record of HPLC testing is submitted. Clarify.	
8.	Provide specifications of drug product in section 3.2.P.5.1	
9.	Justify why the product specifications do not include a test for the assay of preservative contents.	
10.	Provide analytical method of drug product in section 3.2.P.5.2	
11.	Provide complete report of validation studies of the analytical method of drug product since you have	

	submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	
12.	Justify the broad and assymetric peaks in validation studies. Furthermore, you have not determined peak parameters like theoretical plates and tailing factor.	
13	Justify the adaptation of a wide pH range i.e. 6.7 – 7.6 since the desired pH value is 7.4 and results of all batches is also above 7.4.	
14.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	
15.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	
16.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	
15.	Justify the consistent peak tailing in your stability chromatograms.	
16.	Submit valid GMP certificate of the drug substance manufacturer, since the submitted certificate was valid till 12-01-2022.	

Decision of 331st meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	As per submitted Form 5-F, the name of applicant is Winthrox Laboratories and the name of manufacturer is Welmed Pharmaceutical. Correct the Form 5-F along with submission of requisite fee.	Revised Form 5F has been submitted
2.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as	Submitted

	drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
3.	Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
4.	Submit COA of relevant batch of API from both drug substance as well as drug product manufacturer.	Submitted
5.	Justify why pharmaceutical equivalence is performed against a comparator product instead of innovator / reference product.	Due to non availability of reference product we have performed PE studies against brand leader
6.	Provide preservative effectiveness studies.	Submitted
7.	The analytical method for pharmaceutical equivalence specifies UV method while analytical record of HPLC testing is submitted. Clarify.	Revised method and studies are submitted
8.	Provide specifications of drug product in section 3.2.P.5.1	Submitted
9.	Justify why the product specifications do not include a test for the assay of preservative contents.	Revised specifications submitted
10.	Provide analytical method of drug product in section 3.2.P.5.2	Submitted
11.	Provide complete report of validation studies of the analytical method of drug product since you have submitted raw results. Further clarify why the concentration of precision studies and 100% of accuracy study is not as per the target concentration specified in analytical method.	Revised report with correction is submitted
12.	Justify the broad and assymetric peaks in validation studies. Furthermore, you have not determined peak parameters like theoretical plates and tailing factor.	Revised validation report is submitted
13	Justify the adaptation of a wide pH range i.e. 6.7 – 7.6 since the desired pH value is 7.4 and results of all batches is also above 7.4.	pH limit has been revised
14.	Provide stability study data sheets of all the three batches in section 3.2.P.8.3 as per the format specified in CTD guidance document since your data sheets does not specify batch size, API lot number and various other required information.	Submitted
15.	Justify the performance of stability studies at condition specified for impermeable containers while your container closure system is a semi permeable container.	New stability chamber for semi permeable container is to be purchased

16.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data of each batch and time point shall be properly segregated alsong with its relevant raw data sheet and chromatograms so that its evaluation could be carried out, since you have submitted data without following checklist and the submitted data is without any sequence or tagging.	Submitted
15.	Justify the consistent peak tailing in your stability chromatograms.	Tailing factor is less than 2 that's why our peaks are consistent.
16.	Submit valid GMP certificate of the drug substance manufacturer, since the submitted certificate was valid till 12-01-2022.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 30,000/- for correction in the name and address of applicant firm as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

The registration letter will be issued in the light of procedure approved in this meeting for capacity assessment of the contract accepter

Case No. 04 Cases of Form 5-A

662.	**Name and address of Applicant**	**M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.**
	Detail of Drug Sale License	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity: 21-05-2027** **Status:** License to sell drugs as distributor
	Name and address of manufacturer	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
	Name and address of marketing authorization holder	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16462: 07-03-2019
	Fee including differential fee	PKR 50,000/-: 07-03-2019

	Brand Name +Dosage Form + Strength	Unitrexate 500mg Injection
	Composition	Each 20ml vial ml contains: Methotrexate…….500mg
	Finished Product Specification	USP
	Pharmacological Group	Anticancer
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	As per SRO
	International availability	Could not be confirmed
	Me-too status	Could not be confirmed
	Detail of certificates attached	•

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions since the submitted data is as per zone II.	
2.	Submit notarized / legalized sole agency agreement.	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities	
4.	Submit evidence of me-too status	
5.	Submit original, legalized CoPP from the country of origin	

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

663.	**Name and address of Applicant**	**M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.**
	Detail of Drug Sale License	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity: 21-05-2027** **Status:** License to sell drugs as distributor
	Name and address of manufacturer	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.

Name and address of marketing authorization holder	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
Name of exporting country	India
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy No. 16459: 07-03-2019
Fee including differential fee	PKR 50,000/-: 07-03-2019
Brand Name +Dosage Form + Strength	Dacarbazine 200mg Injection
Composition	Each vial contains: Dacarbazine as dacarbazine citrate lyophilized…….200mg
Finished Product Specification	USP
Pharmacological Group	Anticancer
Shelf life	24 months
Demanded Price	As per SRO
Pack size	As per SRO
International availability	USFDA Approved
Me-too status	Decarb Injection by Rotex Pharma
Detail of certificates attached	•

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions since the submitted data is as per zone II.	
2.	Submit notarized / legalized sole agency agreement.	
3.	Submit original, legalized CoPP from the country of origin	

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

Case No. 05 Deferred cases of Import (Human)

664.	**Name, address of Applicant / Importer**	**M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No.: 0002** **Address:** 246-B, Block-6, PECHS, Karachi **Validity:** 15-08-2022 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	South Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 2020-D1-3552) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte 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 3 years. **The name of importing country on CoPP is mentioned as Pakistan.** **GMP:** Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.
	Details of letter of authorization / sole agency agreement	Firm has submitted cLEgalized NOC from M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea which authorises **M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan** to register their products in Pakistan. The authorization letter is valid till 09-11-2022.
	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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 10553 dated 06-04-2021
	Details of fee submitted	Rs.100,000/- dated 24-03-2021

	The proposed proprietary name / brand name	**Hyal Forte Pre Filled Syringe**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe (2ml) Contains 20mg of Sodium Hyaluronate
	Pharmaceutical form of applied drug	Pre-filled syringe
	Pharmacotherapeutic Group of (API)	Hyaluronic acid
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	1's;AS per SRO
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	Hyalgan PFS 20mg/2ml approved by ANSM of France
	For generic drugs (me-too status)	Hyalgan PFS of M.s Matrix Pharma Reg.# 031340
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ℃±2. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence Euflexxa
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Pre-filled syringe
	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

		25ºC ±2ºC / 60% ± 5% RH for 6 months. The real time stability study data is conducted at5ºC ±3ºC / 65% ± 5% RH. The real time stability study data for 3 batches is for 36 months only.

Evaluation by PEC:

- The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate …. 10mg
- Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.
- Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.
- Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.

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

Case No.1. Request for Change in Registration Status of Products from M/s OBS Pakistan (Pvt.) Ltd., Karachi to M/s Aspin Pharma (Pvt.) Ltd., Karachi

Registration Board in its 307th meeting, 317th meeting and 321st meeting deferred the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 for change of registration status of following products from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name as per following details:

Proceedings of M-307:

The cases were referred to Pharmaceutical Evaluation Cell/ QMS for scrutinization/evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Administrative Documents in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of last GMP inspection report dated 01-06-2020 (**Good** Level of Compliance).
ii. Panel Inspection report for renewal of DML dated 26-01-2021.
iii. Section approval of M/s Aspin verified from Licensing Division's letter for renewal of DML (dated 09th June, 2016) confirming following sections; ➢ Tablet (General) ➢ Capsule (General) ➢ Liquid Syrup ➢ Ointment/ Cream.
iv. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 10-12-2020, 07-01-2021 & 16-03-2021.
v. Relevant undertakings & commitments.

[Evaluator: Mr.Abdul Mughees Mudassir (AD to CEO)]

I	II	III	IV	V	VI
S.No.	**Name of Drug(s)**	**Reg. No.**	**Registration History**	**Remarks**	**Status in 293rd Meeting**
1.	Anvol 2.5mg Tablet Each tablet contains: Nebivolol (as HCl)..... 2.5mg (Manufacturer's Specifications)	081780	Initial date of Reg. 07-10-2016 Last Renewal submission date: 30-07-2021 with fee of Rs.15,000/-	Dy.No.3311 (R&I) 11-04.2019 Rs.20,000/-	Stability Studies: To be initiated in January2020 CDP: Performed at OBS. Product is transferring from OBS site to Aspin site through Tech Transfer with same formulation and manufacturing process. Therefore CDP report of OBS site will remain applicable at Aspin site until any change in process or formulation.
Response of the Firm submitted vide R&I Dy.No. 3851 dated 02-02-2021					

1. Stability Data			
Manufacturer of API	CADILA PHARMACEUTICALS LIMITED		
API lot no.	18NV022		
Description of Pack (container closure system)	ALU-ALU blister in unit carton		
Stability Storage Condition	30 ± 2oC/75 ± 5% 40 ± 2oC/75 ± 5%		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Initial, 03 & 06 month		
Batch No.	180DS04	180DS05	180DS06
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	01-2020	01-2020	01-2020
No of Batches	03		
Remarks of Evaluator	Firm has submitted stability protocols, sample submission sheet, Stability Summary Report of each batch, Analytical Test Report of each time point for individual batches, Standard, Assay and Dissolution sample information chromatograms performed at their manufacturing site. However, firm has only submitted 06 months Real time stability studies data at the time of submission.		
2. Comparative Dissolution Profile			
Remarks of Evaluator	Firm has provided CDP of Anvol 10 mg tablets.		
3. Process Validation Protocol			
Remarks of Evaluator	Firm has submitted process validation protocol explaining process design and process qualification. Firm adopted prospective validation approach on three pre-defined, full scale commercial batches. Firm has identified Critical Process Parameters that match with In Process Controls (IPC) outlined in QOS and Product part of Module 3. Sampling and testing plan with statistical process control and deviations have been defined.		
4. Analytical method validation/ verification			
Remarks of Evaluator	Firm has submitted analytical method validation of their own developed method of analysis for Nebivolol tablets with complaint RSD values. Firm has performed system suitability, specificity, Linearity, Accuracy Precision, Intermediate precision, Robustness.		

I	II	III	IV	V	VI
S.No.	**Name of Drug(s)**	**Reg. No.**	**Registration History**	**Remarks**	**Status in 293rd Meeting**
2.	Anvol 5mg Tablet Each tablet contains: Nebivolol (as HCl) …..5mg (Manufacturer's Specifications)	081069	Initial date of Reg. 22-06-2016 Last renewal submission date: 24-03-2021 with fee of Rs.10000/-	Dy.No.2910 (R&I) 08-04.2019 Rs.20,000/-	Stability Studies: To be initiated in January-2020 CDP: Performed at Aspin site and report has been submitted

Response of the Firm submitted vide R&I Dy.No. 3852 dated 02-02-2021

1. Stability Data

Manufacturer of API	CADILA PHARMACEUTICALS LIMITED		
API lot no.	18NV022		
Description of Pack (container closure system)	ALU-ALU blister in unit carton		
Stability Storage Condition	30 ± 2oC/75 ± 5% 40 ± 2oC/75 ± 5%		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Initial, 03 & 06 month		
Batch No.	181DS04	181DS05	181DS06
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	01-2020	01-2020	01-2020
No of Batches	03		

Remarks of Evaluator: Firm has submitted stability protocols, sample submission sheet, Stability Summary Report of each batch, Analytical Test Report of each time point for individual batches, Standard, Assay and Dissolution sample information chromatograms performed at their manufacturing site. However, firm has only submitted 06 months Real time stability studies data at the time of submission.

2. Comparative Dissolution Profile

Remarks of Evaluator	Firm has provided CDP of Anvol 10 mg tablets.
3. Process Validation Protocol	
Remarks of Evaluator	Firm has submitted process validation protocol explaining process design and process qualification. Firm adopted prospective validation approach on three pre-defined, full scale commercial batches. Firm has identified Critical Process Parameters that match with In Process Controls (IPC) outlined in QOS and Product part of Module 3. Sampling and testing plan with statistical process control and deviations have been defined.
4. Analytical method validation/ verification	
Remarks of Evaluator	Firm has submitted analytical method validation of their own developed method of analysis for Nebivolol tablets with complaint RSD values. Firm has performed system suitability, specificity, Linearity, Accuracy Precision, Intermediate precision, Robustness.

Decision of M-307:

Deferred the request with respect to following products due to reasons mentioned alongside each:

S. No.	***Reg. No.***	***Product Name***	***Reasons***
i.	*081780*	*Anvol 2.5mg Tablet*	*Deferred for submission of CDP.*
ii.	*081069*	*Anvol 5mg Tablet*	*Deferred for submission of CDP.*

Proceedings of M-317:

The firm has submitted the CDP for above mentioned product as per following details:

i. Anvol 5 mg Tablet:-

Comparative Dissolution Profile

The comparative dissolution profile was performed for Anvol Tablet 5 mg against the Nebilet Tablet 5 mg (Manufactured by Menarini International Operations Luxembourg). Comparison was performed in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) and phosphate buffer solution (pH 6.8) using 12 samples at 10, 15,20, 30, and 45, minutes.

Sr	Buffer	Time interval	Anvol Tablet 5 mg	Nebilet Tablet 5 mg
i	HCl buffer (pH 1.2)	10 min	104.724 %	90.304 %
		15 min	101.786 %	97.594%

			20 min	102.171%	100.401%
			30 min	101.004%	99.198%
			45 min	98.560%	97.826%
			f1 = 4.334 f2= 59.787		
	ii	Acetate buffer (pH 4.5)	10 min	14.989%	16.591%
			15 min	20.345%	24.168%
			20 min	25.247%	29.447%
			30 min	33.378%	37.338%
			45 min	40.299%	45.062%
			f1 = 11.357 f2= 69.297		
	iii	phosphate buffer (pH 6.8)	10 min	16.903%	27.300%
			15 min	25.203%	25.738%
			20 min	30.454%	31.536%
			30 min	41.340%	45.225%
			45 min	52.297%	61.029%
			f1 = 12.790 f2= 58.200		

Calculation of value revealed that dissimilarity factor f1 and similarity factor f2 fall under acceptable criteria at pH 1.2 and pH 4.5, and pH 6.8.

ii. <u>Anvol 2.5 mg Tablets:-</u>

Comparative Dissolution Profile
The comparative dissolution profile was performed for Anvol Tablet 2.5 mg against the Bystolic Tablet 2.5 mg (Manufactured by Allergan). Comparison was performed in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) and phosphate buffer solution (pH 6.8) using 12 samples at 10, 15,20, 30, and 45, minutes.

Sr	Buffer	Time interval	Anvol Tablet 5 mg	Bystolic Tablet 5 mg
i	HCl buffer (pH 1.2)	10 min	104.776 %	108.433 %
		15 min	102.862 %	101.536%
		20 min	102.170%	101.593%
		30 min	97.618%	105.785%
		45 min	99.772%	97.935%
		f1 = 3.574 f2= 65.351		
ii	Acetate buffer (pH 4.5)	10 min	94.045%	96.498%
		15 min	96.004%	94.615%
		20 min	88.317%	96.279%
		30 min	92.572%	97.499%
		45 min	94.698%	100.328%
		f1 = 7.056 f2= 55.804		
ii	phosphate buffer (pH 6.8)	10 min	97.181%	102.384%
		15 min	97.334%	105.562%
		20 min	97.511%	97.951%
		30 min	88.666%	103.244%
		45 min	103.745%	101.560%
		f1 = 5.767 f2= 56.268		

Calculation of value revealed that dissimilarity factor f1 and similarity factor f2 fall under acceptable criteria at pH 1.2 and pH 4.5, and pH 6.8.

Decision of M-317:

Registration Board deferred the case for submission of justification regarding un-even trends of dissolution profile of both the products i.e., Anvol Tablet 5mg & 2.5mg.

Proceedings of M-321:

Now the firm has submitted their reply vide Diary Number 21691 dated 01 August 2022. The firm has submitted as below:

> *"In this regard, it is stated that; As per Dissolution profile guidelines of US FDA (enclosed herewith, pls. refer to Page 11, Section V), for comparison of dissolution, Dissimilarity factor (f1) and Similarity factor (f2) are calculated for different buffers at different time points and the f1 should be less than 15 while f2 should be greater than 50."*
>
> *"In CDP of our products both f1 and f2 are within limits of US FDA guidelines and hence considered comparable for dissolution of Anvol 2.5mg & 5mg in comparison with its innovator product."*

Decision of M-321:

Registration Board deferred the case for further deliberation.

Current Submission:

The firm has submitted the CDP for above mentioned product as per following details:

i. Anvol 5 mg Tablet:-

<table>
<tr><td colspan="2">Comparative Dissolution Profile</td></tr>
<tr><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>The comparative dissolution profile was performed for Anvol Tablet 5 mg against the Nebil Tablet 5 mg (Manufactured by Getz Pharma). Comparison was performed in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) and phosphate buffer solution (pH 6.8) using 12 samples at 10, 15,20, 30, 45, and 60 minutes.
<table>
<tr><th>Sr</th><th>Buffer</th><th>Time interval</th><th>Anvol Tablet 5 mg</th><th>Bystolic Tablet 5 mg</th></tr>
<tr><td rowspan="7">i.</td><td rowspan="7">HCl buffer (pH 1.2)</td><td>10 min</td><td>89.865%</td><td>90.255%</td></tr>
<tr><td>15 min</td><td>95.894%</td><td>95.014%</td></tr>
<tr><td>20 min</td><td>95.889%</td><td>96.153%</td></tr>
<tr><td>30 min</td><td>96.217%</td><td>92.478%</td></tr>
<tr><td>45 min</td><td>92.716%</td><td>94.172%</td></tr>
<tr><td>60 min</td><td>94.601%</td><td>94.852%</td></tr>
<tr><td colspan="3">f1 = 1.240</td></tr>
</table>
</td></tr>
</table>

			f2= 85.331		
	ii.	Acetate buffer (pH 4.5)	10 min	83.238%	84.269%
			15 min	90.826%	91.518%
			20 min	90.755%	92.311%
			30 min	90.738%	91.486%
			45 min	89.959%	90.665%
			60 min	90.475%	90.969%
			f1 = 0.966 f2= 93.162		
	iii.	phosphate buffer (pH 6.8)	10 min	52.242%	54.494%
			15 min	60.226%	63.531%
			20 min	62.818%	64.348%
			30 min	64.339%	64.819%
			45 min	65.453%	66.610%
			60 min	65.924%	66.239%
			f1 = 2.379 f2= 84.076		
	Calculation of value revealed that dissimilarity factor f1 and similarity factor f2 fall under acceptable criteria at pH 1.2 and pH 4.5, and pH 6.8.				

ii. <u>Anvol 2.5 mg Tablets:-</u>

Comparative Dissolution Profile	
Pharmaceutical Equivalence and Comparative Dissolution Profile	The comparative dissolution profile was performed for Anvol Tablet 2.5 mg against the Nebil Tablet 2.5 mg (Manufactured by Getz Pharma). Comparison was performed in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) and phosphate buffer solution (pH 6.8) using 12 samples at 10, 15,20, 30, 45, 60 minutes.

Sr	Buffer	Time interval	Anvol Tablet 5 mg	Bystolic Tablet 5 mg
	HCl buffer (pH 1.2)	10 min	93.595%	100.296%
		15 min	96.281%	106.131%
		20 min	96.564%	103.846%
		30 min	95.849%	105.538%
		45 min	97.582%	104.513%
		60 min	95.090%	107.256%
		f1 = 8.384 f2= 52.179		
ii.	Acetate buffer (pH 4.5)	10 min	90.084%	90.576%
		15 min	91.052%	91.339%
		20 min	95.387%	95.863%
		30 min	94.434%	95.317%
		45 min	93.575%	94.370%
		60 min	88.519%	86.598%
		f1 = 0.876 f2= 92.791		
iii.	phosphate buffer (pH 6.8)	10 min	71.169%	67.924%
		15 min	76.533%	70.577%
		20 min	77.835%	72.408%
		30 min	81.386%	77.277%
		45 min	83.114%	81.454%
		60 min	80.832%	81.513%
		f1 = 4.672 f2= 69.285		

Calculation of value revealed that dissimilarity factor f1 and similarity factor f2 fall under acceptable criteria at pH 1.2 and pH 4.5, and pH 6.8.

Remarks	The firm has also submitted following documents: 1. Copy of last GMP inspection report dated 09-02-2022. 2. Approval letter for change in title of registration holder from OBS Pakistan (Pvt) Ltd., Karachi to Searle Pakistan Limited, Karachi dated 25-04-2022. 3. Request dated 30-10-2023 regarding withdrawal of Anvol Tablets 2.5mg & 5mg by existing Registration holder. 4. Fresh NOC dated 30-10-2023, issued by M/s Searle Pakistan Limited, Karachi.

Decision: Registration Board decided as under:

i. Cancelled registration of following product from the name of M/s Searle Pakistan Limited (Formerly: M/s OBS Pakistan Pvt. Ltd.), C-14, S.I.T.E, Karachi (DML No.000012).

S. No.	Reg. No.	Product Name & Composition
1.	081780	Anvol 2.5mg Tablet Each tablet contains: Nebivolol (as HCl)..... 2.5mg (As per Innovator's Specifications)
2.	081069	Anvol 5mg Tablet Each tablet contains: Nebivolol (as HCl) …..5mg (As per Innovator's Specifications)

ii. Approved registration of following product in the name of M/s. Aspin Pharma (Pvt.) Ltd., Plot No.10 & 25 Sector 20, Korangi Industrial Area, Karachi (DML No.000045).

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

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

c) Registration letter will be issued after submission of fee of Rs.7500/- for correction in finished product specifications to "As per Innovator's Specifications" in line with the notification No. F.7-11/2012-B&A/DRAP dated 07-05-2021.

S. No.	Product Name & Composition
i.	Anvol 2.5mg Tablet Each tablet contains: Nebivolol (as Hydrochloride)..... 2.5mg
ii.	Anvol 5mg Tablet Each tablet contains: Nebivolol (as Hydrochloride)..... 5mg

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.2. Requirement of Reciprocating Cylinder for Dissolution Testing of U-Progest Softgel Capsules 100mg & 200mg

M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 was issued registrations of "U-Progest Softgel Capsules 100mg & 200mg" by way of contract manufacturing at M/s OBS Pakistan Pvt. Ltd.) C-14, S.I.T.E, Karachi (Currently titled as M/s. Searle Pakistan Ltd.,) vide letter dated 17-08-2021.

In continuation and keeping in view the dissolution method and apparatus adopted by the manufacturer of reference product (i.e., approved by USFDA), the contract manufacturer was directed (vide letter dated 20-08-2021 and reminder dated 04-04-2022) to purchase "Dissolution Apparatus III (Reciprocating Cylinder)" and perform installation, operational and performance qualifications including dissolution test (using a validated analytical method) and submit report within 3 months.

However, despite of the commitment submitted by the registration holder vide letter dated 29-06-2021, the firm neither purchased reciprocating cylinder nor performed quantitative rupture test on U-Progest Soft Gelatin Capsule 100mg and 200mg citing reasons mentioned in column II of below table which have been reviewed and commented vide column III of below table:

I	II	III
S/N	**Information/ Documents Submitted by the Firm**	**Comments/ Remarks of Evaluator/ Reg-I Section**
Rupture Testing as per USFDA:		
1.	Soft gelatin (softgel) capsules can be a means of achieving bioavailability of highly lipophilic drugs that are practically water insoluble. The API is generally dissolve in edible oil. For softgel capsules containing lipophilic drugs, the Division of Bioequivalence (DBE), in the office of Generic Drugs, Center for Drug Evaluation and Research, USFDA, requires from applicants to submit a "quantitative rupture" *in-vitro* drug release test tomeasure the drug released in the dissolutionmedium after the capsule shell ruptures [Dissolution Testing for Generic Drugs: AnFDA Perspective - PMC (nih.gov)].	First reference provided by the firm i.e., Dissolution Testing for Generic Drugs: An FDA Perspective -PMC (nih.gov) is merely an article published online dated 09-04-2011, summarizing how dissolution testing is used for the approval of safe and effectivegeneric drug products in the United States. Regarding rupture test, the article states as under: *"For liquid-filled capsules containing lipophilic drugs, the DBE (Division of Bioequivalence) asks applicants to develop a "quantitative rupture" in vitro drug release test; where, after the rupture of the capsule shell the drug is released and measured in the medium. The DBE believes that this method provides an accurate assessment of the rate at which a capsule shell ruptures by quantifying the amount of active pharmaceutical ingredient (API) dispersed in the surrounding medium. DBE recognizes that developing "quantitative rupture" drug release test for capsules containing lipophilic drugs formulated in oils may be a challenge. Therefore, the DBE encourages the firms to develop an appropriate method using a USP apparatus. Generally, a suitable surfactant in an appropriate concentration can be used in the aqueous medium for these formulations."*
2.	As per USFDA quantitative rupture testing and dissolution testing are the same thing for softgel capsules. Besides this USFDA describes on their website [Dissolution Methods (fda.gov)] for progesterone soft gelatin capsule dissolution methods that "Develop a quantitative rupture test".	Dissolution Methods (fda.gov) is a database developed by USFDA, consisting of FDA recommended dissolution methods for different products. For progesterone capsule, the database states to "develop a quantitative rupture test" (last updated 08-04-2010). In this context, the firm was further advised to submit complete detail/report of quantitative rupture

<table>
<tr><td></td><td>In light of above references Rupture Testing for U-Progest is appropriate to determine dissolution of the product.</td><td>test being performed on aforementioned products along-with method validation report. However, as evident from the report submitted by the firm, instead of developing a quantitative rupture test, the firm has developed, validated and performed the rupture test to determine only the time taken by the capsule to get ruptured, regardless of quantitative analysis of the released content.</td></tr>
<tr><td colspan="3">Orphan Drug:</td></tr>
<tr><td>1.</td><td>i. Only three preparations of progesterone soft gel capsules are available in the local market, two of them being imported in finished form (which are not available regularly due to recurrent shortages) and only one is manufactured locally by OBS Pakistan (Pvt.) Ltd.
ii. OBS is manufacturing these products since November 2014 (using validated testing method including rupture test) and ensuring its availability all the times.

iii. Since its launch, the product has neither declared sub-standard nor any complaint received from Health Care Professional or end user.</td><td>As directed, the firm was verbally communicated to provide quarterly manufacturing record for evaluation.
In response, the firm has submitted copies of batch release certificates for last three batches. Information extracted from the attached certificates is summarized as under:

<table>
<tr><th>Product Name</th><th>Batch No.</th><th>Quantity (Packs)</th><th>Date of Release</th></tr>
<tr><td rowspan="3">U-Progest 100mg Softgel Capsule</td><td>DRD008</td><td>2469</td><td>29-07-2022</td></tr>
<tr><td>DRD009</td><td>2384</td><td>29-07-2022</td></tr>
<tr><td>DRD010</td><td>2464</td><td>30-07-2022</td></tr>
<tr><td rowspan="3">U-Progest 200mg Softgel Capsule</td><td>DSD004</td><td>7076</td><td>29-04-2022</td></tr>
<tr><td>DSD003</td><td>7065</td><td>28-04-2022</td></tr>
<tr><td>DSD005</td><td>4108</td><td>29-04-2022</td></tr>
</table>
</td></tr>
</table>

2.	i. Advice of the Authority for purchasing Dissolution Apparatus III is an additional requisite and financial burden on the firm as it involves huge investment for a producthaving very thin margins. While, Aspin considers producing this product as an obligation to the nation by ensuring uninterrupted availability of an Orphan product. ii. The firm will continue to test the finished product by their validated method which is being used since 2014. Furthermore, the firm hopes that DRAP understands their point of view and will not contend for purchase of an additional and high cost equipment i.e. Dissolution Apparatus III (Reciprocating Cylinder).	Keeping in view the above references and current submission of the firm, it can be concluded that the firm has neither purchased nor intends to purchase Dissolution Apparatus III (Reciprocating Cylinder) regarding which the firm was advised vide letter dated 20-08-2021 reminded vide letter dated 04-04-2022 in the light of *"bioequivalence reviews of Progesterone Capsule"* available on official website of USFDA Progesterone (fda.gov).

Decision: Keeping in view the Dissolution Database available at Dissolution Methods (fda.gov), wherein it has been recommended to develop a quantitative rupture test for 'Progesterone Capsule', Registration Board decided that the firm will be directed to develop, validate, perform and submit quantitative rupture test report of U-Progest Capsule 100mg (R.No.108910) & U-Progest Capsule 200mg (R.No.108911).

Case No. 3. Delegation of Functions to Chairman Registration Board.

Registration Board, in its various meetings (262,276,277,284,288,290,292,295,296 and 297) authorized its Chairman certain functions, under Rule 24(10) of Drugs (Licensing, Registering & Advertising) Rules, 1976, in order to facilitate timely disposal of various cases / post-registration variation cases/ contravention of various provisions of the Drugs Act, 1976.

Later, in its 307th meeting held on 08th - 10th June, 2021, the Board endorsed continuity of delegation of below functions to Chairman Registration Board on behalf of Registration Board.

Sr. No.	Functions
1.	Relaxation / exemption in urdu version only for drugs imported for critical ailments like AIDS, cancer, vaccines, sera etc subject to the condition that same shall be printed at any licensed premises prior to marketing.
2.	Export Registration of finished drugs for following categories except Narcotic, Psychotropic drugs and precursor chemicals. • Generic version / me too drugs of already registered formulations. • Formulations which have already been registered for export purposes. • Formulations which are approved by reference regulatory authorities (as approved by Registration Board) and yet not registered for local sale.

3.	Change of name of the manufacturer of imported drug(s).
4.	Increase/ decrease in shelf life of registered drug.
5.	Grant of additional packing of already registered same drugs/medicines except injectables. (For Veterinary Drugs only)
6.	Action initiated on safety of drugs.
7.	Change of packing from: • PVC to Alu-Alu and vice-versa • strip to blister and vice-versa • strip/blister to bottle and vice-versa • glass bottle to PET/HDPE bottle and vice-versa • PET bottle to HDPE bottle and vice-versa • Vial to ampoule and vice-versa • Glass vial/ampoule to plastic ampoule and vice-versa • Glass vial/ampoule to pre-filled syringe and vice-versa
8.	Change in labeled storage conditions of imported product
9.	Change of source/grant of additional source of half-finished products like pellets, bulk liquid and granules etc. of registered drugs.
10.	Constitution of panel of inspector for product specific inspection, verification of stability data, GMP inspection and dosage form specific inspection of manufacturer abroad etc.
11.	Correction of typographic errors in recording minutes and registration letters like composition, brand names, demanded price, pack size, address (as per DML/DSL) etc or other typing mistakes.
12.	Change in the packing design/packaging components/ change in label, carton/change in shape, colour of Capsule, Tablets and shape of blister/ aluminum foil.
13.	Change of brand names of registered drug(s).
14.	To grant approval of exemption from inspection of manufacturer abroad as per Import Policy for inspection of finished drugs.
15.	To grant approval for issuance of registration letter(s) on recommendation of inspection panel nominated for inspection of manufacturer abroad.
16.	Correction in formulation in accordance with standard formulations approved by reference regulatory authorities i.e. change from uncoated to film/ sugar/enteric coated tablet or vice versa and correction in base / salt / ester / form of API.
17.	Grant of registration of diluents as combo packs for already registered/approved drugs provided that such diluents shall be provided free of cost.
18.	Issuance of registration letters in approved cases of ciprofloxacin granules for oral suspension containing ciprofloxacin base where revision / correction of salt form and granules of the formulation is required after submission of requisite fee. All registration holders of ciprofloxacin granules for oral suspension shall ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator product. • Soya lecithin • Medium chain triglycerides

	• Flavor • Sucrose • Purified water.
19.	**Approval of change of registration status from old title/name of the firm to the new title/name of the firm (If site remains the same)**
20.	Approval of change/correction of finished product specifications in different scenarios mentioned as under: i. Products registered with manufacturer specifications but formulation exist in official monograph (as decided by Registration Board in 267th meeting) ii. Products registered with any pharmacopoeial specification (e.g. USP) but formulation do not exist in that particular pharmacopeia but another pharmacopeia (e.g. BP). iii. Correction in specification while issuance of registration letters in accordance with decisions taken in 264th, 266th & 267th meetings of Registration Board. iv. Product approved/registered with any pharmacopoeial specification but formulation do not exist in any official monograph. v. Change of specifications from one official pharmacopeia to another official pharmacopeia. vi. Manufacturer/innovator specifications for a product are more stringent than official pharmacopoeial specifications.
21.	Grant of renewal of registration (locally Manufactured) which have been received within time as required under Rule 27 of Drug (LR&A) Rules 1976.
22.	Grant of extension in cases of contract manufacturing of already registered products if these are on same terms and conditions.
23.	Change of contract manufacturer/ manufacturing site of already registered products.
24.	Issuance of show cause notice for cancellation of registration after termination of agency authorization by Manufacturer / Product License Holder.
25.	Issuance of show cause notice for cancellation of registration after cancellation of DML

With respect to S.No. 19 of the above-mentioned functions, the Chairman has been authorized for "Approval of change of **registration status** from old title/name of the firm to the new title/name of the firm (If site remains the same)".

However, as per existing practice, if name/ title of the applicant is changed before issuance of registration letter (i.e., during the process of evaluation or during processing for issuance of registration letter after approval by the RB), the case is processed at Division level with full fee of registration.

Accordingly, instant case is submitted for endorsement by the Registration Board regarding approvals for change of title/ name of the applicant before issuance of registration letter.

Decision: **Registration Board endorsed the delegation of following function to Chairman Registration Board on behalf of Registration Board:**

"Approval of pre-registration variation in title/name of the firm (If manufacturing site remains the same)"

Case No. 4. Verification of Duplicate fee challans.

Registration Board in its 264th meeting held on 28th -29th December, 2016 decided to adopt following procedure for verification of fee challan:

a. Respective section shall report non-traceability of application from record and receipt of application will be verified / confirmed from R&I section, DRAP.
b. For verification of deposited fee, copy of bank challan / deposit slip shall be forwarded to Budget & Account Division for verification from record. In case of non-traceability by aforementioned Division, applicant will get verification of challan from National Bank of Pakistan / Allied Bank. In both cases, applicant will submit an undertaking that these challans have not been and shall not be used for any purpose/ processing of case(s), other than the registration of applied drug.
c. For all those cases whose challans are neither verified by Budget & Account Division nor by National Bank of Pakistan / Allied Bank, and in order to resolve this issue, it is advisable that applicant may deposit fee for missing challan to avoid any financial non-compliance and consideration of registration application at same position as confirmed by R&I section, DRAP.
d. If Registration Board has already approved application subject to verification of fee, then Chairman is authorized for issuance of registration letters after verification of fee challan / submission of fee as recorded above.

Later on, in its 285th meeting held on 03rd – 4th October, 2018, Registration Board decided as under:

> "**The Board decided and directed also to accept original yellow challan slips as evidence / confirmation of fee submission."**

However, in a number of cases (especially those of differential fee), the applicants only submitted copies of fee challan. When such cases were referred (in line with the decision of 264th meeting) for verification of fee from Budget and Accounts Division, DRAP, the said Division responded as under:

> **"You are requested to provide original deposit slip/ challan for verification because as per SOP, verification can only be done on original (Pink color/ Drap copy) deposit slip/ challan. If not possible, please proceed in the light of decision made in 264th meeting of Registration Board."**

In order to dispose of such cases, the applicants were directed to submit original MOH/ DRAP's acknowledged receipts of their application having endorsement of fee by the statistical officer and registration letters were issued accordingly.

Instant case is placed before the Registration Board for endorsement of above-mentioned practice of considering original MOH/ DRAP's (R&I) acknowledged receipts of applications having endorsement of fee by the statistical officer.

Decision: Registration Board decided that in future for all those cases where the applicant only holds photocopy of fee deposit slip/ challan, reference shall be forwarded to DDO/Deputy Director, Budget & Accounts Division, DRAP for verification of photocopy fee deposit slip/ challan.

Case No. 5. Deferred Applications of M/s Apex Pharmaceuticals (Pvt) Ltd., Karachi

Registration Board in its 277th meeting held on 27th - 29th December, 2017 deferred the following registration applications of M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No. D-21-A/1, S.I.T.E., Super Highway, Karachi (DML No.000746) for submission of source of pellets and requisite documents and fee.

S. No.	Name of drug(s) & Composition	Proposed Pack size	Proposed Price	Date of application, Diary No. Form

				& Fee
1.	Esopex 20mg Capsule Each capsule contains: Esomeprazole……20 mg (Proton pump inhibitor)	As per PRC	As per PRC	16-04-2012 Dy.No.715 Rs.8000/- Rs. 12,000/- Form-5
2.	Esopex Capsule Each capsule contains: Esomeprazole……40 mg (Proton pump inhibitor)	14's	As per PRC	16-04-2012 Dy.No.685 Rs.8000/- Rs. 12,000/- Form-5
3.	Lowcid 20mg Capsule Each capsule contains: Omeprazole… .....20 mg (Antipeptic / Ulcerant)	As per PRC	As per PRC	16-04-2012 Dy.No.714 Rs.8000/-+ 12,000/- Form-5

The applicant has now submitted following information/ details in line with the decision of decision of M-277 of Registration Board

Sr.No	Name of drug(s) & Composition	Fees Details
1.	Esopex 20mg Capsule Each capsule contains: Enteric Coated Pellets of Esomeprazole Eq. to Esomeprazole…..... 20mg **Source of Pellets:** **Vision Pharmaceuticals**	• Rs.30,000/-(Slip # 726025932433) for correction in label claim. • Rs.10,000/-(Slip# 1778637613) for differential Registration Fee.
2.	Esopex 40mg Capsule Each capsule contains: Enteric Coated Pellets of Esomeprazole Eq. to Esomeprazole…..... 40mg **Vision Pharmaceuticals**	• Rs.30,000/-(Slip # 00402717) for correction in label claim. • Rs.10,000/-(Slip# 9785271533) for differential Registration Fee.
3.	Lowcid 20mg Capsule Each capsule contains:	• Rs.30,000/-(Slip # 09656776580) for correction in label claim. • Rs.10,000/-(Slip# 70459688308) for differential Registration Fee.

	Enteric Coated Pellets of Omeprazole Eq. to Omeprazole…..... 20mg **Vision Pharmaceuticals**	

i. Capsule (General) Section Approval confirmed from Licensing Division's letter dated 20-09-2021.
ii. Last GMP inspection dated 20-04-2023 (status rated as "Good")
iii. DML renewed w.e.f. 27-08-2017

Decision: Registration Board approved the grant of registration for below-mentioned products of M/s Apex Pharmaceuticals, Pharmaceuticals (Pvt) Ltd., Plot No. D-21-A/1, S.I.T.E., Super Highway, Karachi (DML No.000746):

Sr.No	Name of drug(s) & Composition
1.	Esopex 20mg Capsule Each capsule contains: Enteric Coated Pellets of Esomeprazole Eq. to Esomeprazole…..... 20mg **Source of Pellets:** Vision Pharmaceuticals, Islamabad
2.	Esopex 40mg Capsule Each capsule contains: Enteric Coated Pellets of Esomeprazole Eq. to Esomeprazole…..... 40mg **Source of Pellets:** Vision Pharmaceuticals, Islamabad
3.	Lowcid 20mg Capsule Each capsule contains: Enteric Coated Pellets of Omeprazole Eq. to Omeprazole…..... 20mg **Source of Pellets:** Vision Pharmaceuticals, Islamabad

Case No. 6. Request of M/s Akhai Pharmaceuticals (Pvt) Ltd., Balochistan for Consumption of Imported Controlled Drug Substance 'Ketamine Hydrochloride'

Registration Board in its 323rd meeting held on 06th-08th December, 2022 considered the subject mentioned request of M/s Akhai Pharmaceuticals (Pvt) Ltd., A-248 & A-256 to A-259, Hub Industrial Trading Estate Lasbella Balochistan wherein the firm informed that they have been granted registration of Ketlar (Ketamine) Injection; Reg. No.014966 (valid till 30th June, 2025) by way of contract manufacturing at

M/s. Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupra Road, Lahore. The registration was granted for contract manufacturing well before classification of Ketamine under controlled drug substances

Furthermore, M/s Neutro Pharma had imported 50kg of Ketamine Hydrochloride on their behalf and for the exclusive manufacturing of their above stated product. Primary and secondary packaging materials are also available with them. **In this context, the firm requested for permission to consume the available quantity of Ketamine Hydrochloride**.

However, Ketamine and its salts have been declared as "Psychotropic substances" vide SRO Number 1350(I)/2021 dated 15th October, 2021. Furthermore, as per existing contract manufacturing policy, notified vide SRO 1347(I)/2021, dated 15.10.2021, Rule 20 A 2(c) states that:

> ***"Contract manufacturing of controlled drugs (narcotic drug or psychotropic substances or precursor chemicals) shall not be allowed;"***

In this context, following comments were also received:

Comments Received from Controlled Drugs Division:

The Committee for Allocation of Quota of Controlled Substances allocates the quota to those firms having valid drug manufacturing license and valid drug registration as per SOP.

Comments Received from QA&LT Division:

Consumption of any API is linked primarily to valid license to manufacture a drug and secondarily to valid registration of that drug. If as a consequence of any change in some rule/regulation or policy the status of both these prerequisite (DML and MA) for any drug becomes void/invalid, the consumption of respective APIs could not be allowed for that particular drug.

Foregoing in view, Registration Board decided as under:

"Keeping in view the classification of "Ketamine and its salts" under psychotropic substances (vide SRO 1350(I)/2021 dated 15th October, 2021) and Rule 20A(2)(c) of Drugs (L, R & A), Rules, 1976, Registration Board decided as follows:

- *Decided to issue show cause notice to the firm under Section 7 (11)(d) of the Drug Act, 1976 that why the registration of their product "Ketlar Injection (Reg. No. 014966)" may not be cancelled. Management of the firm shall also be given the opportunity of personal hearing in the forthcoming meeting of the Board under section 42 of the Drugs Act, 1976.*
- *Recommended QA&LT Division to decided case for already imported material as per Drug (I&E) Rules, 1976."*

Accordingly, show cause and personal hearing notice was issued dated 18-07-2023 andQA&LT Division was communicated the above-mentioned decision, in response to which, Deputy Director (QA/LT) Division has stated as under:

> *"It is pertained to mention that Division of QA & LT is helpless to implement and comply the above decision of Board as Drugs (Import & Export) rules 1976 are silent regarding disposal of this API Ketamine Hcl being Psychotropic material. The import, export, trans-shipment and disposal/destruction of Narcotic/Psychotropic material is governed under Control of Narcotic Substances Act, 1997 in collaboration with Controlled Drug Division of DRAP. It is therefore requested to reconsider the decision and matter may be referred to concerned division for implementation."*

In this context, it is submitted that the field force is under the administrative control of QA&LT Division and regulatory actions could not be carried out without the filed force. Furthermore, Assistant Director (I&E) is also under the administrative control of QA&LT, which is working as Licensing Authority on behalf of CEO, DRAP after delegation of power. Therefore, the fate of imported controlled drug substance "Ketamine" may be decided by QA&LT Division in consultation with Controlled Drugs Division, DRAP and Ministry of Narcotics Control.

Keeping in view the above-mentioned stance of PE&R and QA & LT Division, the case was referred for collective wisdom of the Authority on the matter, please.

DRAP's Authority in its 173rd meeting held on 10th October, 2023 considered and decided the case as under:

> ***"The request of M/s Akhai Pharmaceuticals was not acceded to as the Drugs (Licensing, Registering & Advertising) Rules, 1976 does not contain the enabling provision to allow contract manufacturing of controlled substance."***

Furthermore, with respect to the show-cause along-with personal hearing notice issued to the firm to appear before the Registration Board on 25th July, 2023 at 2.00 P.M., the case was considered by the Board in its 330th meeting held on 24th-26th July, 2023 wherein no one appeared on behalf of the firm. Accordingly, the Board decided as under:

> ***"Registration Board decided that the firm shall be provided one final opportunity of personal hearing in the next meeting."***

In line with the above-mentioned decision, the firm has been called for personal hearing on 20th December, 2023 at 3:00 P.M.

Proceedings of 333rd Meeting of Registration Board:

While, the meeting was in process, M/s Akhai Pharmaceuticals (vide letter dated 19-12-2023) informed that on 19th December, 2023, they came to know that the case regarding Ketlar Injection has been included in agenda of 333rd meeting. They did not receive the notice of personal hearing yet and no flight is available from Karachi to Islamabad on 20-12-2023. Accordingly, the firm requested to give time for hearing in the next meeting of Registration Board.

Furthermore, Mr. Haroon Dugal, Advocate Supreme Court, as counsel for M/s Akhai Pharmaceuticals also submitted an application for adjournment (received on 20-12-2023) stating that the counsel is representing petitioner in the titled case for which no personal hearing notice has been duly received so far. Furthermore, petitioner's daughter wedding has been scheduled for the same date as the hearing. Accordingly, the petitioner is unable to travel to attend the hearing scheduled on 20-12-2023 as no flight is available from Karachi to Islamabad on the afore mentioned date. Due to the foregoing circumstances, the petitioner will be unable to appear before this Honourable Court. Hence, it is respectfully requested that the case may kindly be adjourned to a date convenient to this Honourable Court in the interest of justice, equity and fair play.

Decision: Registration Board decided that the firm shall be provided one final opportunity of personal hearing in the next meeting of Registration Board.

Case No. 7. Request of M/s Wnsfeild Pharmaceuticals, Hattar Regarding Withdrawal of Tamoxi Tablet Approved in 323rd Meeting of Registration Board

Following product of M/s Wnsfeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar was approved by the Registration Board in its 323rd meeting held on 06th-08th December, 2022 as per following detail:

Name and address of manufacturer/ Applicant	M/s WnsFeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar.
Brand Name + Dosage Form + Strength	TAMOXI 20mg tablet
Composition	Each film-coated tablet contains: - Tamoxifen (As Citrate) 20mg

Diary No. Date of R & I & fee	Dy. No. 287 dated 25-11-11, Rs. /- 8000/- Dy. No. dated Differential fee Rs. 12,000/- vide challan No. 0548767 dated 14-10-2015. (Duplicate dossier, R & I record of initial and differential fee submission along with fee challans required) R&I verified
Pharmacological Group	Selective estrogen-receptor modulator
Type of Form	Form 5
Finished product Specification	USP specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	USFDA approved (NOLVADEX 10mg & 20mg, uncoated tablet) **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**, Also MHRA approved
Me-too status	Tamoxidex 20mg Tablet of Pacific pharma, Lahore. Registration No. 098134
GMP status	Not provided
Remarks of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each tablet contains: Tamoxifen (As Citrate) .....20mg, along with revision of master formulation and manufacturing outlines accordingly. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
Decision: Approved as per following label claim: **Each tablet contains:** **Tamoxifen (as Citrate)..... 20mg** • **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from film coated to uncoated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with copy of latest GMP inspection report conducted within last three years.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	

Later on, in 329th meeting of Registration Board held on 06th-08th June, 2023, separate application of "Tamoxifen 20mg Tablet" was approved in favour of M/s Wnsfeild, Hattar:

Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase- V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
Brand Name +Dosage Form + Strength	TAXOFIN tablet 20mg

Composition	Each film coated tablet contains: Tamoxifen as Citrate Salt (USP)…..20mg
Diary No. Date of R& I & fee	Dy No. 14531 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900626 dated 05-03-2019.
Pharmacological Group	Hormone antagonists and related agents Anti-estrogens ATC Code L02BA01
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Tamoxifen 20mg film-coated Tablets MHRA Approved PL 00142/0272
Me-too status	Shamoxifen Tablet 20mg M/s Shaheen Pharmaceuticals, Swat Reg. No. 97089
GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
Remarks of the Evaluator[xxiii].	Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

Now, the firm has requested (vide application dated for withdrawal of registration application of "Tamoxifen Tablet" approved in 323rd meeting of Registration Board.

Decision: Registration Board acceded to the above-mentioned request of M/s WnsfeildPharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar forwithdrawal of registration application of "Tamoxifen Tablet" (Dy. No. 287 dated 25-11-11), approved in 323rd meeting of Registration Board.

Case No.8. Request for Change in Registration Status of Ikodil 10mg and 20mg Tablets from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachito M/s Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area Karachi, throughcontract manufacturing.

M/s. Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area Karachi has requested to change the product registration status of Ikodil 10mg and 20mg Tablets from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi to their name. However, the product will continue to manufacture at the same manufacturing site i.e. M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi through contract manufacturing.

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of DML of M/s OBS Pakistan Pvt Ltd., (DML # 000012) renewed w.e.f. 26-10-2020 and M/s Aspin Pharma Pvt Ltd, (DML# 000045) renewed w.e.f 31-03-2020.
ii. Copy of DML (000045) of M/s Aspin Pharma (Pvt) Ltd, Karachi. Plot No. 10&25 Korangi Industrial Area, Karachi-Pakistan renewed w.e.f 31-03-2020.
iii. Copy of GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan Ltd.) dated 15-02-2022 on the basis of inspection conducted on 08-10-2021. Copy of last GMP inspection report dated 09-02-2022.
iv. Copy of renewal of DML letter dated 26-10-2020 confirming "Tablet (General) Section of M/s Searle Pakistan Ltd (Formerly OBS Pakistan Ltd.), and same on the GMP Certificate dated 15th Feb, 2022. v. Copy of DRAP's letter dated 16th June, 2021 for renewal of DML of M/s Aspin Pharma Pvt Ltd, mentioning Tablet (General) among sections
vi. Copy of DRAP's letter dated 16th June, 2021 for renewal of DML of M/s Aspin Pharma Pvt Ltd, mentioning Tablet (General) among sections
vii. Approval letter for change in title of registration holder from OBS Pakistan (Pvt) Ltd., Karachi to Searle Pakistan Limited, Karachi dated 25-04-2022.
viii. NOC from M/s. The Searle Company Ltd; Karachi for transfer of Ikodil 10mg and 20mg Tablets on the name of M/s. Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area, Karachi issued on 31-10-2022. Fresh NOC dated 30-10-2023, issued by M/s Searle Pakistan Limited, Karachi.
ix. Request dated 30-10-2023 regarding withdrawal of Anvol Tablets 2.5mg & 5mg by existing Registration holder.
x. Contract Agreement between M/s Aspin Pharma Pvt Ltd, and M/s Searle Pakistan Ltd (Formerly OBS Pakistan Ltd).
xi. Relevant undertakings & commitments.

The cases were referred to Pharmaceutical Evaluation Cell / QMS for scrutiny/evaluation. Detail of submitted documents and remarks of evaluators have been mentioned as under:

[Evaluator: Mr. Asadullah (DD-QMS)]

I	II	III	IV
S.No.	**Reg. No.**	**Product Name & Composition** **(As per initial Registration letter)**	**Registration Trail**
1.	058053	Ikodil 10mg Tablets Each tablet contains: - Nicorandil 10mg (BP Specification)	**Initial Reg. Date: 30-08-2009** Remarks of RRR Section Regarding Renewal Status: Renewal application of year 2019 received on 26-03-2019 i.e., within time, under the Rule 27 of Drug (L,R&A) Rules 1976
	Name, address of Applicant / Marketing Authorization Holder	**M/s** Aspin Pharma Pvt Pharma Pvt Ltd. **Address: Plots # 10 & 25, Sector 20 Korangi**	

		Industrial Area Karachi – 74900, Pakistan
	Name, address of Manufacturing site.	M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi-75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)
	Status of the applicant	☐Manufacturer ☐Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm	**For transfer of registration:** The inspection report concluded M/s Aspin Pharma is running at a good level of GMP compliance based on the inspection conducted on 09.02.2022.
	Evidence of approval of manufacturing facility	Applicant has provided copies of letter dated 13th April, 2018 and GMP certificate of dated 31st Jan, 2020 showing Tablet (General) among Formulation sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35206 R&I:dated 05-12-2023 Dy No 20010 R&I dated 11-08-2023
	Details of fee submitted	**For transfer of registration and contract manufacturing** PKR.75,000/-:DS 7096444743 dated 26-09-22
	The proposed proprietary name / brand name	Ikodil 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains:

		Nicorandil 10mg
	Pharmaceutical form of applied drug	White color pentagonal shaped core tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Anti anginal
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	10's and 14's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Ikoril 10mg Tablets, Sanofi Aventis UK,
	For generic drugs (me-too status)	Nicoril 10mg Tablets (Ferozesone Pharma (Pvt.) Ltd, (Reg# 045951)
	Name and address of API manufacturer.	M/s RPG Life Sciences Limited, MIDC Land, Thane Belapur Road, Navi Mumbai, India
	1.5.11-Proposed Label	Submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Drug Substance Nicorandil was synthesis at manufacturing site of M/s RPG Life Sciences India, who has provided information summaries related to structure, properties, solubility, characterization, and impurities. DS specification was assigned as per BP monograph and accordingly analytical method was developed and verified. CoA of DS used in stability studies was provided from both DS and DP manufacturer. Working standard characterized against BP reference standard was used by M/s RPG. Stability studies were conducted for accelerated and long-term conditions. Applicant M/s OBS Pharma provided summaries of information related to description of finished dosage form, composition, manufacturing process flow and critical steps and intermediates, batch formula, Specification were assigned as per BP monograph, analytical procedure and its verification, CoA of raw DS, batch analysis, working standard, container closure system and stability studies of drug product. Information summaries for analytical method procedures and validation were provided. The finished product is recommended to store below 30^{O}C with a

		shelf life of 18 months.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubility and other physio chemical properties, physical form, manufacturers and their roles. Synthesis process flow of Nicorandil and a brief on manufacturing process was provided. Characterization of DS and related impurities using IR, UV and Spectroscopy. The acceptable limits for each type of impurities were assigned and analytical results of three batches were DS shown conformance to these limits. Elemental impurities, Genotoxicity and Nitrosamine impurities were also analysed and DS was within acceptable limits, non-mutagenic and free from nitrosamine impurities respectively. DS specifications and analytical method was developed as per BP monograph. Analytical method for assay and related substance was verified by HPLC. Method for excipients specifications, CoAs and Standard testing procedures. Certificate of analysis of working standard was provided. Container closure system comprises white polyethylene bags in a HDPE Drums, with a storage condition f 2-8^{o}C in tightly closed container for 36 months. Specifications and testing methods of packaging material was provided. Three batches were subjected to stability studies for long term and accelerated conditions.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches (Mfg Date: 05-2013) of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 25^{o}C ± 2^{o}C / 60% ± 5% RH for 6 months. The DS was not stable at accelerated condition as significant changes were observed. **The real time stability data is conducted at 5^{o}C ± 3^{o}C for 72 months and the DS remained stable for 72 months.** The DS was placed in transparent inner and outer polyethylene bags in aHDPE Container.
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, formulation, justification of excipients, and batch formula, manufacturing procedure, critical parameters of manufacturing process was provided. Dry mixing and compression method was used for tablet manufacturing. Pharmaceutical equivalence and comparative dissolution were studied against the

<table>
<tr><td></td><td></td><td>reference product. CDP was comparable with the reference product. Manufacturing process, process control and validation protocol was provided. Control of excipients, specifications, analytical procedures were provided. Information for control of drug product, analytical procedure, Dissolution method as per BP, and verification of analytical method was provided. Batch analysis, justification of specifications, working standard, container closure system and stability studies were provided.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>The comparative dissolution profile was performed against the Ikorel 10mg Tablets manufactured by Sanofi, UK. The comparison was performed in three dissolution mediums at pH 1.2, pH 4.5 and pH 6.8 using 12 samples at 10, 15, 30 and 45 minutes. The results revealed are as under:-
<table>
<tr><th>Sr</th><th>Medium</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="5"></td><td rowspan="5">Acidic buffer
(pH 1.2)</td><td>10 min</td><td>95%</td><td>94 %</td></tr>
<tr><td>15 min</td><td>99%</td><td>90%</td></tr>
<tr><td>30 min</td><td>100%</td><td>91%</td></tr>
<tr><td>45 min</td><td>100%</td><td>91%</td></tr>
<tr><td colspan="3">f1 = 8
f2= 55</td></tr>
<tr><td rowspan="5">ii</td><td rowspan="5">Acetate buffer
(pH 4.5)</td><td>10 min</td><td>98%</td><td>88 %</td></tr>
<tr><td>15 min</td><td>97%</td><td>89%</td></tr>
<tr><td>30 min</td><td>96%</td><td>89%</td></tr>
<tr><td>45 min</td><td>97%</td><td>89%</td></tr>
<tr><td colspan="3">f1=9
f2=54</td></tr>
<tr><td rowspan="4">iii</td><td rowspan="4">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>97%</td><td>89 %</td></tr>
<tr><td>15 min</td><td>101%</td><td>90%</td></tr>
<tr><td>30 min</td><td>102%</td><td>92%</td></tr>
<tr><td>45 min</td><td>102%</td><td>90%</td></tr>
</table>
</td></tr>
</table>

					f1=11 f2=50
	Analytical method validation/verification of product	The firm has verified analytical method and reported for drug substance and finished drug product.			

STABILITY STUDY DATA			
Manufacturer of API	M/s RPG Life Sciences Limited, MIDC Land, Thane Belapur Road, Navi Mumbai, India		
API Lot No.	NRL3101809		
Description of Pack (Container closure system)	Alu/PVC blister in unit carton		
Stability Storage Condition	Long Term: 25°C ± 2°C / 60% ± 5%RH Intermediate: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Long Term: 18 moths Intermediate: 12 months		
Frequency	Long Term: 0, 3, 6, 9, 12,18 (Months) Intermediate: 0, 3, 6, 9,12 (Months)		
Batch No.	B1576	026C03	C0001
Batch Size	200000 Tablet	200000 Tablet	200000 Tablet
Manufacturing Date	10-2018	02-2020	01-2021
Date of Initiation	29-10-2018	22-02-2020	11-05-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued to M/s RPG Life Science, issued by the Drug Control Administration, Government of Telangana, India. Validity upto 24-06-2024. This certificate mentioned Nicorandil in the approved products list.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of the commercial invoice specifying purchase of 20 Kg Nicorandil by M/S OBS Pakistan, cleared from DRAP Karachi office dated Jan-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

I	**II**	**III**	**IV**
S.No.	**Reg. No.**	**Product Name & Composition** **(As per initial Registration letter)**	**Registration Trail**
2.	058054	Ikodil 20mg Tablets Each tablet contains: - Nicorandil 20mg (BP Specification)	**Initial Reg. Date: 30-08-2009** **Initial Reg. Date: 30-08-2009** Remarks of RRR Section Regarding Renewal Status: Renewal application of year 2019 received on 26-03-2019 i.e., within time, under the Rule 27 of Drug (L,R&A) Rules 1976
	Name, address of Applicant / Marketing Authorization Holder	**M/s** Aspin Pharma Pvt Pharma Pvt Ltd. **Address: Plots # 10 & 25, Sector 20 Korangi Industrial Area Karachi – 74900, Pakistan**	
	Name, address of Manufacturing site.	M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi-75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)	
	Status of the applicant	☐Manufacturer	

		☐Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm	**For transfer of registration:** The inspection report concluded M/s Aspin Pharma is running at a good level of GMP compliance based on the inspection conducted on 09.02.2022.
	Evidence of approval of manufacturing facility	The applicant has provided copies of letter dated 13th April, 2018 and GMP certificate of dated 31st Jan, 2020 showing Tablet (General) among Formulation sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35206 R&I:dated 05-12-2023 Dy No 20010 R&I dated 11-08-2023
	Details of fee submitted	**For transfer of registration and contract manufacturing** PKR.75,000/-:DS 920220247117 dated 06-09-22
	The proposed proprietary name / brand name	Ikodil 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nicorandil 20mg
	Pharmaceutical form of applied drug	White color square-shaped core tablets with score line on one and plane on the other sides plain.
	Pharmacotherapeutic Group of (API)	Anti anginal
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	10's and 14's
	Proposed unit price	As per DPC

	The status in reference regulatory authorities	Ikoril 20mg Tablets, Sanofi Aventis UK,
	For generic drugs (me-too status)	Nicoril 20mg Tablets (Ferozesone Pharma (Pvt.) Ltd, (Reg# 045952)
	Name and address of API manufacturer.	M/s RPG Life Sciences Limited, MIDC Land, Thane Belapur Road, Navi Mumbai, India
	1.5.11-Proposed Label	Submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Drug Substance Nicorandil was synthesis at manufacturing site of M/s RPG Life Sciences India, who has provided information summaries related to structure, properties, solubility, characterization, and impurities. DS specification was assigned as per BP monograph and accordingly analytical method was developed and verified. CoA of DS used in stability studies was provided from both DS and DP manufacturer. Working standard characterized against BP reference standard was used by M/s RPG. Stability studies were conducted for accelerated and long-term conditions. Applicant M/s OBS Pharma provided summaries of information related to description of finished dosage form, composition, manufacturing process flow and critical steps and intermediates, batch formula, Specification were assigned as per BP monograph, analytical procedure and its verification, CoA of raw DS, batch analysis, working standard, container closure system and stability studies of drug product. Information summaries for analytical method procedures and validation were provided. The finished product is recommended to store below $30^{O}C$ with a shelf life of 18 months.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubility and other physio chemical properties, physical form, manufacturers and their roles. Synthesis process flow of Nicorandil and a brief on manufacturing process was provided. Characterization of DS and related impurities using IR, UV and Spectroscopy. The acceptable limits for each type of impurities were assigned and analytical results of three batches were DS shown conformance to these limits. Elemental impurities, Genotoxicity and Nitrosamine impurities were also analysed and DS was within acceptable limits, non-mutagenic and free from nitrosamine impurities respectively. DS specifications

		and analytical method was developed as per BP monograph. Analytical method for assay and related substance was verified by HPLC. Method for excipients specifications, CoAs and Standard testing procedures. Certificate of analysis of working standard was provided. Container closure system comprises white polyethylene bags in a HDPE Drums, with a storage condition f 2-8°C in tightly closed container for 36 months. Specifications and testing methods of packaging material was provided. Three batches were subjected to stability studies for long term and accelerated conditions.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches (Mfg Date: 05-2013) of drug substance at both accelerated as well as real-time conditions. The accelerated stability data was collected at 25°C ± 2°C / 60% ± 5% RH for 6 months. The DS was not stable at accelerated conditions as significant changes were observed. The real-time stability data was collected at 5°C ± 3°C for 72 months and the DS has remained stable for 72 months. The DS was placed in transparent inner and outer polyethene bags in an HDPE Container.
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, formulation, justification of excipients, and batch formula, manufacturing procedure, critical parameters of manufacturing process was provided. Dry mixing and compression method was used for tablet manufacturing. Pharmaceutical equivalence and comparative dissolution were studied against the reference product. CDP was comparable with the reference product. Manufacturing process, process control and validation protocol was provided. Control of excipients, specifications, analytical procedures were provided. Information for control of drug product, analytical procedure, Dissolution method as per BP, and verification of analytical method was provided. Batch analysis, justification of specifications, working standard, container closure system and stability studies were provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The comparative dissolution profile was performed against the Ikorel 20mg Tablets manufactured by Sanofi, UK (Batch 1NF7C Exp Date 02-2023). Comparison was performed in three dissolution medium at pH 1.2, pH 4.5 and pH 6.8 using 12 samples

<table>
<tr><td></td><td></td><td>at 05, 10, and 15 minutes. The results revealed are as under:-

<table>
<tr><th>Sr</th><th>Medium</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="4"></td><td rowspan="4">Acidic buffer
(pH 1.2)</td><td>05 min</td><td>91%</td><td>85 %</td></tr>
<tr><td>10 min</td><td>102%</td><td>95%</td></tr>
<tr><td>15 min</td><td>105%</td><td>97%</td></tr>
<tr><td colspan="3">The sample and reference products both achieved 85% within 15 minutes.</td></tr>
<tr><td rowspan="4">ii</td><td rowspan="4">Acetate buffer
(pH 4.5)</td><td>05 min</td><td>91%</td><td>99%</td></tr>
<tr><td>10 min</td><td>98%</td><td>105%</td></tr>
<tr><td>15 min</td><td>98%</td><td>105%</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="4">iii</td><td rowspan="4">Phosphate Buffer (pH 6.8)</td><td>05 min</td><td>94%</td><td>86%</td></tr>
<tr><td>10 min</td><td>98%</td><td>91%</td></tr>
<tr><td>15 min</td><td>99%</td><td>90%</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="5">The CDP result revealed that both sample and reference product achieved 85% release within 15 minutes therefore f1 and f2 not required to be calculated</td></tr>
</table>
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>The firm has verified analytical methods for drug substance and drug products.</td></tr>
</table>

STABILITY STUDY DATA

Manufacturer of API	M/s RPG Life Sciences Limited, MIDC Land, Thane Belapur Road, Navi Mumbai, India
API Lot No.	NRL3101809
Description of Pack (Container closure system)	Alu/PVC blister in unit carton
Stability Storage Condition	Long Term: 25°C ± 2°C / 60% ± 5%RH Intermediate: 30°C ± 2°C / 65% ± 5%RH

Time Period	Long Term: 18 moths Intermediate: 12 months		
Frequency	Long Term: 0, 3, 6, 9, 12,18 (Months) Intermediate: 0, 3, 6, 9,12 (Months)		
Batch No.	B1576	026C03	C0001
Batch Size	200000 Tablet	200000 Tablet	200000 Tablet
Manufacturing Date	10-2018	02-2020	01-2021
Date of Initiation	29-10-2018	22-02-2020	11-05-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued to M/s RPG Life Science, issued by the Drug Control Administration, Government of Telangana, India. Validity upto 24-06-2024. This certificate mentioned Nicorandil in approved products list.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 20 Kg Nicorandil by M/S OBS Pakistan, cleared from DRAP Karachi office dated Jan-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Proceedings of M-333:

Registration Board was apprised that significant change was reported at 6th month of accelerated study conducted at 25ºC ± 2ºC / 60% ± 5% RH. While, real-time stability data was collected at 5ºC ± 3ºC for 72 months and the drug substance remained stable for 72 months. In this context, ICH Q1A(R2) guidelines states as under:

"If significant change occurs between 3 and 6 months' testing at the accelerated storage condition, the proposed re-test period should be based on the real time data available at the long term storage condition."

Decision: Registration Board decided as under:

i. **Cancelled registration of following products from the name of M/s Searle Pakistan Limited (Formerly: M/s OBS Pakistan Pvt. Ltd.), C-14, S.I.T.E, Karachi (DML No.000012).**

S. No.	Reg. No.	Product Name & Composition
1.	058053	**Ikodil 10mg Tablets** **Each tablet contains: -** **Nicorandil..... 10mg** **(BP Specification)**
2.	058054	**Ikodil 20mg Tablets** **Each tablet contains: -** **Nicorandil..... 20mg** **(BP Specification)**

ii. **Approved registration of following products in the name of M/s. Aspin Pharma (Pvt.) Ltd., Plot No.10 & 25 Sector 20, Korangi Industrial Area, Karachi (DML No.000045) by way of contract manufacturing at M/s Searle Pakistan Limited (Formerly: M/s OBS Pakistan Pvt. Ltd.), C-14, S.I.T.E, Karachi (DML No.000012).**
   a) **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
   b) **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

S. No.	Product Name & Composition
i.	**Ikodil Tablet 10mg** **Each tablet contains: -** **Nicorandil..... 10mg** **(BP Specifications)**
ii.	**Ikodil Tablet 20mg** **Each tablet contains: -** **Nicorandil..... 20mg** **(BP Specifications)**

iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).**

M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd, A-46, S.I.T.E, North Karachi					
1.	023941	Famila 28F Tablets Each tablet contains: Levonorgestrel…0.15mg Ehtinylestradiol…0.03mg Each Tablet contains: Ferrous Fumarate BP 75.0mg equivalent to 24.37mg of Ferrous Iron	Famila 28F Tablets Each tablet contains: Levonorgestrel B.P…0.15mg Ehtinylestradiol B.P…0.03mg Each film coated Tablet contains: Ferrous Fumarate BP 75.0mg equivalent to 24.37mg of Ferrous Iron **(BP Specification)**	06-02-2002 20-10-2021	Fee Rs 10,000/- deposited dated 23-02-2023 R&I Dy. No. 5693 dated 28-02-2023

Remarks:-

The firm has submitted the reference of FDA which contains levonorgestrel 0.3mg, Ethinyl Estradiol 0.03mg and Ferrous Fumarate 75 mg, While the product Famila 28F tablet contains levonorgestrel 0.15mg, Ethinyl Estradiol 0.03mg and Ferrous Fumarate 75 mg.

The firm has also submitted the reference of WHO PQ product having same formulation, but the tablet is sugar coated**.**

Decision of 104th PRVC:-

The Chairman Registration Board on recommendation of committee deferred the cases for submission of evidence of film coated tablet formulation from RRAs.

Reply of Firm

M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd, A-46, S.I.T.E, North Karachi vide Dy. No. 21458 dated 30-08-2023 has referred to this office Letter No. F-104-PRVC/2023 (PR-I) dated 16-08-2023 regarding their Application No.5693 dated 28-02-2023 on subject "Change in Specification of Registered Drug namely Famila 28 F Tablets, Reg. No. 023941". The firm has provided the following details: -

1. **Registration of Drug Product:**

   The Drugs Registration Board granted registration of drug namely Famila 28 F Tablets via Letter No. F.6-33/94-Reg.-II (M-168) dated 06-02-2002. The Registration Number of Famila 28 F Tablet is 023941.

2. **Registered Packing of Drug Product:**

The Drug Product Famila 28 F has composite packing of 21+7 Tablets. The 21 Tablet are hormone and used for birth control while the 7 Tablets are Iron Supplement.

3. Registered Composition of Drug Product:

Hormone Tablet (Active Medicine w.r.t. Birth Control)	Iron Supplement Tablet (In-active Medicine w.r.t. Birth Control)
Each Tablet Contains: Levonorgesgestrel 0.150 mg and Ethinylestradiol 0.030 mg	Each Tablet contains: Ferrous Fumarate 75 mg equivalent to 24.37 mg of elemental Iron

4. Pharmaceutical Form:

Hormone Tablet (Active Medicine w.r.t. Birth Control)	Iron Supplement Tablet (In-active Medicine w.r.t. Birth Control)
Uncoated Tablets	Film Coated Tablets

References for Un-Coated Hormone Tablets:

i. LENEST 30 ED levonorgestrel/ ethinylestradiol 150 micrograms/30 micrograms tablet composite pack (TGA Australia Approval attached)
https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=233113&agid=%28PrintDetailsPublic%29&actionid=1

ii. INDAYO (Levonorgestrel and Ethinyl Estradiol, 0.15 mg and 0.03 mg) Tablets (Copy of Product Monograph attached)
https://pdf.hres.ca/dpd_pm/00034356.PDF

iii. NORDETTE-28 (levonorgestrel 0.15 mg and ethinyl estradiol 30 mcg) tablet
https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/018782s039lbl.pdf

iv. MIN-OVRAL 28 (150 mcg levonorgestrel and 30 mcg ethinyl estradiol) tablets
https://www.pfizer.ca/files/MIN-OVRAL_PI_E_219902_04-Dec-2018.pdf

https://pdf.hres.ca/dpd_pm/00045904.PDF

v. LEVORA 0.15/30-28 (levonorgestrel and ethinyl estradiol) tablets
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=31679b9f-58c9-4bf1-8c2c-f5a216ff4cd3##

5. REQUIREMENT FOR US-AID GLOBAL HEALTH SUPPLY CHAIN PROGRAM A are same as
Famila 28F Tablets (Refer attachment)**.**

i. Type: **Combined Oral Contraceptive Tablets**
ii. Presentation: Twenty-eight (28) tablets per monthly cycle/blister pack consisting of twenty-one (21) tablets containing estrogen and progestin and seven (7) placebo tablets
iii. Components:
Hormone Tablets
Estrogen – The estrogen portion of the combined tablets will contain

30 mcg of ethinyl estradiol

AND

Progestin – The progestin portion of the combined tablets will contain

150 mcg of levonorgestrel

Placebo Tablets

Iron tablets- The blister pack will also contain (7) iron tablets of 75 mg ferrous fumarate.

Reference:

https://www.ghsupplychain.org/sites/default/files/2017-04/Annex%204_Product_Specifications_Technical%20Requirements_OCs_FINAL_NT.pdf

6. International Availability of Composite Pack of Hormone and Iron Supplement Tablets

i. Joyeaux Tablets (levonorgestrel and ethinyl estradiol tablets and ferrous fumarate tablets*)

***** The ferrous fumarate tablets do not serve any therapeutic purpose.

***Reference- 1:** https://www.drugs.com/pro/joyeaux.html#s-43678-2

Referenec-2:https://xiromed.com/usa/products/levonorgestrel-and-ethinyl-estradiol-tablets-usp-0-1mg-and-0-02mg-ferrous-fumarate-tablets/

ii. LO/OVRAL FE Tablets (ethinyl estradiol; levonorgestrel; ferrous fumarate)

Reference:
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=browseByLetter.page&productLetter=L

iii. LO/OVRAL-28 AND FERROUS FUMARATE Tablets (norgestrel and ethinyl estradiol tablets and ferrous fumarate tablets*).

*Ferrous Fumarate tablets are Inactive Tablet

Reference:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/018206s022lbl.pdf

iv. OVRAL 28 Tablets (Levonorgestrel and Ethinylestradiol Tablets with Ferrous Fumarate Tablets)

Reference: https://labeling.pfizer.com/ShowLabeling.aspx?id=14833

The same combination available in EMA List of nationally authorised medicinal products

	i. **Rigevidon 21+7 Tablets (Levonorgestrel and Ethinylestradiol Tablets + Ferrous Fumarate Tablets)** **Reference:** **1)** https://gedeonrichter-com-ec.translate.goog/rigevidon-21-7-oral/?_x_tr_sl=es&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=sc **2)** https://www-nhathuocankhang-com.translate.goog/thuoc-tranh-thai/rigevidon-21-7?_x_tr_sl=vi&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=sc **7. Requirement of Iron Supplement with Hormone Tablets** **Reference:** Nutrients | Free Full-Text | Iron-Containing Oral Contraceptives and Their Effect on Hemoglobin and Biomarkers of Iron Status: A Narrative Review (mdpi.com) The above details indicate that the combination of Hormone Tablet and Iron Supplement Tablet (Levonorgestrel and Ethinylestradiol Tablets with Ferrous Fumarate Tablets) is an internationally available drug product (copy of above evidences enclosed) Therefore, in the light of above evidences, you are requested to kindly approve the Pharmacopoeia Specification of Famila 28 F Tablets as given in above section 6.

Remarks:-

The firm has submitted the references of combinations with inert, uncoated tablets. Whereas, the formulation is present in WHO PQ having same formulation, but the tablet is sugar coated.

Decisions of 108th PRVC: -

The Chairman Registration Board on recommendation of committee refer the case to Registration Board for deliberation on the matter**.**

Decision: Registration Board decided to give personal hearing to the firm to explain their position on the said matter.

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s Vetz Pharmaceutical (Pvt.) Ltd, Q-1, SITE, Kotri Sindh, 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 2-8/2011-Lic dated 24-06-2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 09-03-2022

Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Viva-CF Injection 100ml Each 100ml contains: Fructose .....50gm Vitamin C 6g	Purchase order from Oman	Dy. No. 1275(27.10.2023) Rs.30,000/- (08.08.2023) Rs.45,000/- (20.10.2023)
2.	Hepaplus Injection 100ml Each 100ml contains: Acetylmethionine. ..... 4.5g DL-Methionine. .....1.5g Sorbitol .....21g Cocarboxylase. 0.3g	Purchase order from Oman	Dy. No. 1276(27.10.2023) Rs.30,000/- (08.08.2023) Rs.45,000/- (20.10.2023)
3.	Met-Vetz Injection 100ml Each ml contains: Methionine..... 200mg	Purchase order from Oman	Dy. No. 1277(27.10.2023) Rs.30,000/- (08.08.2023) Rs.45,000/- (20.10.2023)
4.	Orni-Vetz Injection 100ml Each 100ml contains: Betaine..... 15mg Arginine (Hydrochloride) ..... 33.3mg Ornithine (Hydrochloride)..... 11.8mg Citrulline..... 10mg Sorbitol .....200mg Metacresol 3mg	Purchase order from Oman	Dy. No. 1278(27.10.2023) Rs.30,000/- (08.08.2023) Rs.45,000/- (20.10.2023) Required fee of Rs 7500/-
5.	URO-Vetz Injection 100ml Each ml contains: Methenamine. 400mg	Purchase order from Oman	Dy. No. 1279(27.10.2023) Rs.30,000/- (11.08.2023) Rs.45,000/- (20.10.2023)

6.	C-Vita Injection 100ml Each ml contains: Ascorbic acid.....200mg	Export order required	Dy. No. 1345(24.11.2023) Rs.75,000/- (15.11.2023)
7.	Amino-C Injection 100ml L-Ornithine aspartate..... 20mg L-Arginine hydrochloride..... 75mg L-Citrulline.....5mg Acetyl Methionine.....10mg Choline citrate. 10mg	Purchase order from Oman	Dy. No. 1346(24.11.2023) Rs.30,000/- (11.08.2023) Rs.45,000/- (20.10.2023) Rs.75,000/- (10.11.2023) fee for change strength
8.	Chondro Plus- Vetz Injection 10ml Each 100ml contains: Chondroition Sulphate A.....75.00gm Glucosamine Sulphate.....75.00gm	Purchase order from UAE	Dy. No. 1347(24.11.2023) Rs.30,000/- (08.08.2023) Rs.45,000/- (20.10.2023) Rs.75,000/- (10.11.2023) fee for change strength

Decision: Registration Board deliberated that although the aforementioned formulations are neither metoo formulations nor available in any RRA. However, the said formulations do not require special manufacturing conditions and the firm has purchase order from Oman & UAE. Hence, to increase the export revenue of the country, Registration Board approved above products exclusively for export purpose only subject to the submission of fee of Rs. 7500/- for Omi-Vetz Injection 100ml.

Case No.02: Registration of Drug (s) of M/s Helix Pharma (Pvt.) Ltd, Plot No. A-56, S.I.T.E. Karachi, for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-20/84-Lic dated 28-12-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 01-08-2023
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.	Mirogab Tablets 15mg Each film coated tablet contains: Mirogabalin (as besylate) 15mg	Purchase order from Sri Lanka	Dy. No. 1356(29.11.2023) Rs.75,000/- (30.10.2023)
2.	Mirogab Tablets 5mg Each film coated tablet contains: Mirogabalin (as besylate) 5mg	Purchase order from Sri Lanka	Dy. No. 1357(29.11.2023) Rs.75,000/- (30.10.2023)
3.	Mirogab Tablets 2.5mg Each film coated tablet contains: Mirogabalin (as besylate) 2.5mg	Purchase order from Sri Lanka	Dy. No. 1358(29.11.2023) Rs.75,000/- (30.10.2023)
4.	Mirogab Tablets 10mg Each film coated tablet contains: Mirogabalin (as besylate) 10mg	Purchase order from Sri Lanka	Dy. No. 1359(29.11.2023) Rs.75,000/- (30.10.2023)

Decision: Registration Board deliberated that although the aforementioned formulations are neither me too formulations nor available in any RRA. However, the said formulationsdo not require special manufacturing conditions and the firm has purchase order fromSri Lanka. Hence, to increase the export revenue of the country, Registration Board approved above products exclusively for export purpose only.

Case No.03: Registration of Drug (s) of M/s Daneen Pharma (Pvt.) Ltd, Plot No. 27, Sunder Industrial Estate, Sunder Raiwind Road, Lahore, Contract Manufacturing by M/s Genix Pharma (Pvt.) Ltd, Plot No. 44-45-B, Korangi Creek 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 2-12/93-Lic dated 30-09-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 06-06-2023

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.	LMF 400mcg Tablet Each film coated tablet contains: L-methyl folate as calcium 400mcg	Purchase order from Afghanistan	Dy. No. 1392(30.11.2023) Rs.30,000/- (31.08.2023) Rs.45,000/- (20.10.2023)
2.	Gemcin 320mg Tablet Each film coated tablet contains: Gemifloxacin mesylate equivalent to 320mg of gemifloxacin	Gemimir Tablet of M/s Fahmir Pharma	Dy. No. 1392(30.11.2023) Rs.30,000/- (04.09.2023) Product has been withdrawn by EMA. But, the firm has submitted that it is still available in USFDA.

Decision: Registration Board decided as follows:

- **Registration Board approved product at sr. no. 2 exclusively for export purpose only subject to submission of export order endorsed by regulatory authority of country of Import.**
- **Although the formulation at sr. no. 1 is neither me too formulation nor available in any RRA. However, the said formulation does not require special manufacturing conditions and the firm has purchase order from Afghanistan. Hence, to increase the export revenue of the country, Registration Board approved the product exclusively for export purpose only.**

Case No.04: Registration of Drug (s) of M/s Medisure Laboratories Pakistan (Pvt.) Ltd, A-115, 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;
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 2-2/2001-Lic dated 21-07-2023
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 14-02-2023

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.	Perasure 1.5g Injection Each vial contains: Cefoperazone as sodium (USP)..... 1000mg Sulbactam as sodium (USP) 500mg	Purchase order from UAE	Dy. No. 1453(01.12.2023) Rs.75,000/- (24.11.2023)
2.	Neurocoline 1000 mg Tablet Each film coated tablet contains: Citicoline (as sodium)..... 1000mg	Purchase order from Philippines	Dy. No. 1454(01.12.2023) Rs.30,000/- (02.11.2023) Rs.45,000/- (24.11.2023)

Decision: Registration Board deliberated that although the aforementioned formulations are neither me too formulations nor available in any RRA. However, the said formulationsdo not require special manufacturing conditions and the firm has purchase order fromUAE & Philippines. Hence, to increase the export revenue of the country, Registration Board approved above products exclusively for export purpose only.

DEFERRED CASES

CASE OF 108-PRVC

Case No.1: Registration of Drug (s) of M/s Medisure Laboratories Pakistan (Pvt.) Ltd, A-115, 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. 232-252 /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- 237/C). Approval of relevant section verified from letter No. F 2-2/2001-Lic dated 21-07-2023 (Page 238/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 14-02-2023 (Page 239 /C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do	Provided (Pages. 240/C)

not resemble with already registered brands in importing country.	

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
102.	Restat 20mg Tablet Each film coated tablet contains: Atorvastatin (as atorvastatin calcium trihydrate) 20mg	Winstor tablet by M/s Sanofi	Dy. No. 1300/23 (14.11.2023) Rs.30,000/- (30.10.2023)
103.	Restat 10mg Tablet Each film coated tablet contains: Atorvastatin (as atorvastatin calcium trihydrate) 10mg	Winstor tablet by M/s Sanofi	Dy. No. 1301/23 (14.11.2023) Rs.30,000/- (30.10.2023)

The applied names resemble with already registered brand names Crestat (Rosuvastatin) of M/s CCL Pharmaceuticals, Lahore.

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. 102-103 for Export Purpose Only subject to submission of more brand names (which do not resemble with already registered drugs)."

UPDATED STATUS

Firm has state that their subject product has been approved by Philippines FDA and they have been granted Certificate of Product Registration (CPR) with the brand name of "RESTAT" in Philippines.

That, brand name "RESTAT" is their registered product in Philippines -FDA. They have submitted the copy of Certificate of Product Registration (CPR) for reference.

Decision: Approved, as the same brand has been approved by Philippines FDA and the Certificate of Product Registration (CPR) with the brand name of "RESTAT" in Philippines has been submitted

Case No. 01: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Report of Manufacturer Abroad.

Following imported product approved in 297th meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/	Panel of Inspector(s)/ Date of inspection
1.	M/s. HealthBee ProjectsPvt. Ltd. 65-S Quaid-e- Azam Industrial Estate, Kot Lakhpat, Lahore./ M/s. Shandong Luoxin Pharmaceutical Group Stock Co., Ltd Luoqi Road, High & New Technology Industries Development Zone Linyi City, Shandong Province, PR China.	Gemcitabee for injection 0.2g Each vial contains:- Gemcitabine as Hydrochloride 0.2g	(i) Mr. Abdullah Abro, Deputy Director (MD&MC), Drug Regulatory Authority of Pakistan, Islamabad. (ii) Malik Muhammad Asad, Deputy Director (Pharmacy Services), Drug Regulatory Authority of Pakistan, Islamabad.

Accordingly, inspection was carried out by inspection panel dated 01st& 10th March, 2023 and final remarks of the panel are as under:-

FINAL REMARKS:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture drugs and appeared to comply the GMP requirements. Hence, the panel recommends that the Registration Board may grant the registration of applied product namely Injection Gemcitabine 0.2g (Gemcitabine as Hydrochloride) of M/s. HealthBee Projects Pvt. Ltd. 65-S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.

Panel further strongly recommends on-site inspection in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm within one year as virtual inspection can never replace physical/in-person inspection.

Registration Board in its 330th meeting deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendation regarding the grant of registration as per law.

Accordingly letter issued to the panel members to remand back the case to inspecting panel for clear and candid recommendation regarding the grant of registration as per law. In response the panel members inform that;

Panel reply is as under:

Reference to Circular No. letter No.F.3-2/2005-Reg-I/Vol-II dated 27th September, 2022 regarding virtual inspection of manufacturers abroad for registration of finished drugs and biologicals guidelines, which reads as:

(a) DRAP will conduct remote virtual inspections for verification of GMP compliances by overseas manufacturing facilities. This Remote Virtual Inspection (RVI) program will utilize a risk based

approach based on the complexity of each product. The applicants will ensure adequate communication tools both for desktop review of information and video inspection at the site including video scopes, inspection cameras, borescope, fiberscope etc. depending on the operations of the manufacturing site. However, in order to avoid and potential series threat to the public health where the manufacturing sites cannot basis remotely, hybrid inspection approach or and on-site inspection will be considered.

(b) In the light of facts mentioned herein above, it is submitted that the inspection of the said premises was carried out virtually and the compliance to GMP standards was assessed, however, keeping in view the sensitivity of the products and the risks associated, the panel is of the opinion that the firm may be inspected physically before grant of registration.

Decision: Registration Board deliberated the matter in details and decided to refer the recommendations of the panel to the Authority for guidance.

Case No. 02:- Request of M/s. A&S Animal Health, 61-A Westwood Colony Thokar Niaz Baig Lahore/ Registration of Drugs under the Drugs Act, 1976.

M/s. A&S Animal Health, 61-A Westwood Colony Thokar Niaz Baig Lahore request for registration of imported veterinary drug from the name of previous importer M/s. Forward Solutions, 80-A, Judicial Colony, Thokar Niaz Baig, Lahore to their name. The details are as under:-

S. No.	Regn. No.	Name of Drug (s)/ Composition as per initial registration letters.	Manufacturer as per initial registration letter	Manufacturer/ Product License Holder as per CoPP & Shelf Life	Approved pack size as per initial registration letter	Initial date of registration/ renewal status
1.	078290	Lincomicina 150 Ganadexil Oral Powder Each gram contains:- Lincomycin (as HCL)… 150mg	Manufactured by M/s. Industrial Veterinaria, S.A.-Invesa Esmeralda, 19, E-08950 Esplugues De Llobregat (Barcelona) Spain.	Market Authorization Holder &Manufacturer:- M/s. Industrial Veterinaria, S.A. Esmeralda, 19 08950 Esplugues De Llobregat (Barcelona) Spain). 03 years	100g 1 Kg 5 Kg	22-05-2014 13-03-2019

M/s. A&S Animal Health, 61-A Westwood Colony Thokar Niaz Baig Lahore has deposited required fee of Rs.150,000/- and submitted the following documents:-

(i) No Objection Certificates from M/s. Forward Solutions, 80-A, Judicial Colony, Thokar Niaz Baig, Lahore
(ii) Original legalized free sale certificate for veterinary medicinal products issued by Spanish Authority.
(iii) Original legalized certificate of GMP compliance of a manufacturer.
(iv) Original legalized sole agency letter.
(v) Original termination of sole distribution.
(vi) Copy of Drug Sale License valid upto 20th October, 2027.
(vii) Undertaking.
(viii) Site Master File along with Form-5A.

Registration Board in its 330th meeting deliberated the matter and decided to defer for submission of cancellation application of Lincomicina 150 (Reg. No. 078290) from M/s. Forward Solutions, 80-A, Judicial Colony, Thokar Niaz Baig, Lahore so that new registration may be granted to M/s. A&S Animal Health, 61-A Westwood Colony Thokar Niaz Baig, Lahore.

In response the firm has submit of cancellation application of Lincomicina 150 (Reg. No. 078290) from M/s. Forward Solutions, 80-A, Judicial Colony, Thokar Niaz Baig, Lahore.

Decision: Registration Board deliberated the matter and decided as under:

i. **Approved the registration in the name of M/s. A&S Animal Health, 61-A Westwood Colony Thokar Niaz Baig Lahore.**
ii. **Cancellation the registration in the name of M/s. Forward Solutions, 80-A, Judicial Colony, Thokar Niaz Baig, Lahore.**

Import & Vet-II SECTION

Case No. 03: M/s. sanofi-aventis Pakistan limited request for Inkjet Printing on Secondary Packaging (Printed Cartons) of OreloxPaediatric Suspension 40mg/5ml – Reg No. 015709

M/s sanofi-aventis Pakistan limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi has requested to allow inkjet printing of the following text (both in English and Urdu) on in-transit stock of OreloxPaediatric Suspension. This is being done for better understanding on reconstitution of OreloxPaediatric Suspension by the consumers and to increase patient compliance.

Instructions for reconstitution/use:

- **Add previously boiled cool water, half way up to the bottle marking.**
- **Shake vigorously, add more water up to the engraved marking and shake again.**
- **Use the calibrated syringe for administration.**

ہوا ٹھنڈا پانی ڈال کر اچھی طرح ہونل کو ہلائیں۔ دیئے گئے نشان تک ہلائے سے ابال ہونل پر

میں موجود کیلیبریٹڈ سرنج کا استعمال کریں۔ خوراک کے لئے ڈبے

Stock details are as follows:

Product Name	Batch No	Quantity (Packs)
OreloxPaediatric Suspension Cefpodoxime 40mg/5ml	3N57A	35,532

The firm has submitted the following documents:

- Fee of Rs. **7,500/-** (Seven Thousand and Five Hundred Rupees only) via e-deposit slip No. **370459960100** along with Differential fee of **Rs. 2,500/-** (Two Thousand and Five Hundred Rupees only**)** via e-deposit No. **1064681649** dated **31-10-2023** – (original e-deposit slips attached)
- Copy of registration,and last renewal letter
- Valid Drug Manufacturing License
- Drug Sales License renewal application with acknowledgement receipt

The firm has requested to allow inkjet printing on in-transit stock of OreloxPaediatric Suspension at their licensed premises i.e., M/s sanofi-aventis Pakistan limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi, Pakistan (Drug Manufacturing License No.000007).

Decision:

Registration Board acceded to the request for inkjet printing on in-transit stock of Orelox Paediatric Suspension (Reg No. 015709) at their licensed premises i.e., M/s sanofi-aventis Pakistan limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi, Pakistan (Drug Manufacturing License No.000007). The Board advised the firm to locally print following text both in English and Urdu:

Instructions for reconstitution/use:

- **Add previously boiled cool water, half way up to the bottle marking.**
- **Shake vigorously, add more water up to the engraved marking and shake again.**
- **Use the given calibrated syringe for administration.**

کو ہلائیں۔ ٹھنڈا پانی ڈال کر اچھی طرح بوتل پہلے سے ابال ہوا نشان تک بوتل ہر دیئے گئے

استعمال کریں۔ موجود سرنج کا لیے ڈبے میں خوراک کے

This permission shall be valid for given stock on Secondary Packaging (Printed Cartons) of Orelox Paediatric Suspension.

Additional agenda

Case 1. Registration of drug under drug act 1976

Registration Board in 312th meeting considered & approved the following product of M/s Lab Diagnostic Systems (SMC) Pvt Ltd, Taxila Rawalpindi as per following details:

Name of Importer/Manufacturer	Product Name & Composition	Decision

M/sLab Diagnostic Systems (SMC) Pvt. Ltd. 111B, Hali Road, Westridge 1, Rawalpindi Cantt., Pakistan **Manufacturer & Product License Holder:** M/s Jiangsu Hengrui Pharmaceuticals Co., Ltd. No. 38, Huanghe road, Economic and technological Development Zone, Lianyungang	EthiodizedPoppyseed Oil Injection Each vial contains: EthiodizedPoppyseed Oil Injection **10ml** (contains Iodine 480mg/ml)	Approved with innovator's specifications as per import policy for inspection of Manufacturer abroad and verification of local storage facility for shelf life of 6months with storage condition below 30 °C

ii. As the product contains Ethiodized Poppyseed Oil Injection, the case was forwarded to the Controlled Drugs Division for their opinion on whether the NOC (No Objection Certificate) from the Ministry of Narcotics Control is required or not.

iii. The Controlled Drugs Division attached a letter from the Ministry of Narcotics Control, which states that "all parts of the poppy plant are restricted except for its seeds. However, any preparations containing more than 0.2% of Morphine or Diacetylmorphine are prohibited."

iv. The importer was asked to submit a reply in light of the letter from the Ministry of Narcotics Control.

v. Now, they have submitted a letter from the manufacturer abroad, which shows that their product does not contain Morphine or Diacetylmorphine.

Decision: Registration Board keeping in view the comments and letter forwarded by the Division of Controlled Drugs, DRAP and the reply of the firm, endorsed the approval granted in 312th meeting with innovator's specifications as per import policy for inspection of Manufacturer abroad

RRR Section

Case No. 1 Renewal applications submitted by M/s. Theramed Pharmaceuticals (Pvt) Ltd.,45-Km Multan Road Lahore.

M/s Theramed Pharmaceuticals (Pvt) Ltd.,45-Km Multan Road Lahore has submitted renewal applications of their following registered drugs after the due date but within sixty days. Accordingly under Rule 27 of Drug (Licensing, Registering & Advertising) Rules 1976, the firm has submitted the differential fee on 30.10.2023 mentioned in the table. The decision is recorded below against each case:

Sr.No.	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s. Theramed Pharmaceuticals (Pvt) Ltd.,45-Km Multan Road Lahore.					
1.	091445	Alz 2mg Tablet	27/07/2018	Rs.15000/- Dated 27.07.2023	Renewal is granted

		Each tablet contains Alprazolam… 2mg		Vide Dy No.18971 & Rs.30000/- dated 30.10.2023 Vide Slip No.070435241	w.e.f.27.07.2023 to 26.07.2028
2.	091444	Alz 1mg Tablet Each tablet contains Alprazolam… 1mg	27/07/2018	Rs.15000/- Dated 27.07.2023 Vide Dy No.18971 & Rs.30000/- dated 30.10.2023 Vide Slip No.44210180	Renewal is granted w.e.f.27.07.2023 to 26.07.2028
3.	091443	Alz 0.5mg Tablet Each tablet contains Alprazolam… 0.5mg	27/07/2018	Rs.15000/- Dated 27.07.2023 Vide Dy No.18971 & Rs.30000/- dated 30.10.2023 Vide Slip No.8622163178	Renewal is granted w.e.f.27.07.2023 to 26.07.2028
4.	091442	Alz 0.25mg Tablet Each tablet contains Alprazolam… .0.25mg	27/07/2018	Rs.15000/- Dated 27.07.2023 Vide Dy No.18971 & Rs.30000/- dated 30.10.2023 Vide Slip No.9418627328	Renewal is granted w.e.f.27.07.2023 to 26.07.2028
5.	091441	L-Pam 2mg Tablet Each tablet contains Lorazepam……2mg	27/07/2018	Rs.15000/- Dated 27.07.2023 Vide Dy No.18971	Renewal is granted w.e.f.27.07.2023 to 26.07.2028

				& Rs.30000/- dated 30.10.2023 Vide Slip No.05734611497	
6.	091440	L-Pam 1mg Tablet Each tablet contains Lorazepam…..1mg	27/07/2018	Rs.15000/- Dated 27.07.2023 Vide Dy No.18971 & Rs.30000/- dated 30.10.2023 Vide Slip No.597690702	Renewal is granted w.e.f.27.07.2023 to 26.07.2028

Item No: III Division of Quality Assurance & Laboratory Testing

S. No.	Case title
	OOS Investigations
01	MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD PHENERZINE ELIXIR, BATCH NO. 037, MANUFACTURED BY M/S EPOCH PHARMACEUTICALS (PVT) LTD., KARACHI.
02	MANUFACTURE & SALE OF SUB-STANDARD FENTOS TABLETS, BATCH NO. 599 MANUFACTURED BY M/S. HISUN PHARMACEUTICAL INDUSTRIES, GADOON-PAKISTAN
	ROUTINE CASES
03	MANUFACTURE & SALE OF SUBSTANDARD PARAPALS INFUSION, BATCH NO. LI-100, LI-101 & LI-102, MANUFACTURED BY M/S INVENTOR PHARMA, KARACHI.
04	IMPORT OF REGISTERED PRODUCTS THROUGH FAKE/FORGED INVOICES BY M/S. BIOCURE PHARMACEUTICALS, LAHORE.
05	SUBSTANDARD GENTAMYCIN EAR DROPS MANUFACTURED BY M/S. AMROS PHARMA KARACHI – QCB ISLAMABAD CASE.
06	SUBSTANDARD MENTIN FORTE TABLET MANUFACTURED BY M/S. UNEXO LABS LAHORE – QCB ISLAMABAD CASE.

Case No. 01: <u>MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD PHENERZINE ELIXIR, BATCH NO. 037, MANUFACTURED BY M/S EPOCH PHARMACEUTICALS (PVT) LTD., KARACHI.</u>

The Assistant Director, DRAP Karachi took sample from export consignment of Ms. Taqwa Pharma & Surgical, Karachi on 28-05-2022 for purpose of test/analysis on Form-3. The Federal Government Analyst has declared following samples of Phenerzine Elixir as of **"Adulterated & Substandard quality"**.

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Report No. & Date
Phenerzine Elixir	M/s Epoch Pharmaceuticals (Pvt) Ltd., Karachi	009751	037	03-2022	03-2024	No.KQ-6-22-000141 dated 14-07-2022

02. 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	Specification	Result	Reference
1	**Description**	Slightly orange color liquid	Slightly orange color liquid containing numerous black particles visible with naked eye. Black particles also recovered on filter paper. **Does not comply.**	Mfg. Specs
2	**Identification**	The identification test must identify Promethazine HCL.	Complies	Mfg. Specs
3	**pH**	4.2 to 5.5	4.51-complies	Mfg. Specs
4	**Assay** Promethazine HCL (Label claim 5mg/5ml)	90.0% to 110.0%	97.06% Complies.	Mfg. Specs

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

03. M/s. Epoch Pharma, Karachi replied to AD and requested for retesting to Appellate Lab NIH Islamabad.

04. 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 dated 02-09-2023.

05. M/s. Epoch Pharma, Karachi provided scientific justification for sugar particles:

"The sugar is made of Hydrogen, Carbon and Oxygen atoms, when sugar burns completely, then the product of the reaction are carbon dioxide and water. however, in reality sugar tends not to burn completely and a black mass of products of incomplete oxidation of sugar result and black particles are formed."

06. Federal Government Analyst, CDL, Karachi submitted the reply about OOS investigation stated that:

"Sample was declared substandard and adulterated on the basis of description. therefore, OOS investigation does not apply."

07. Technical Evaluation of the case:

- The product was declared adulterated and sub-standard on the basis of description i.e. Slightly orange color liquid containing numerous black particles visible with naked eye. Black particles also recovered on filter paper.
- Justification given by the firm is not scientific, this phenomenon occurs only when sugar is burnt in absence of water, first its own water of crystallization is evaporated dissolving some of the crystals (caramelization) and ultimately removed, and in next step it is completely burnt/combusted leaving black carbon, but this case is the manufacturing of syrup, sugar in water.
- FGA, CDL Karachi submitted that sample was declared substandard and adulterated on the basis of description. Therefore, OOS investigation does not apply

Proceedings and Decision of 333rd Meeting of Registration Board.

- Out of Specification (OOS) investigations and testing records submitted by M/s. Epoch Pharma, Karachi and CDL, DRAP Karachi were presented before Registration Board. The Board deliberated on the OOS investigation and did not agreed with the OOS investigation submitted by the firm M/s Epoch Pharma, Karachi.
- The Board did not accede to the firm's request for appellate testing and decided to issue show cause notice to M/s. Epoch Pharma, Karachi under Section 42 of the Drugs Act, 1976 and called them for personal hearing before Registration Board in its forthcoming meeting.

CASE NO. 02 MANUFACTURE & SALE OF SUB-STANDARD FENTOS TABLETS, BATCH NO. 599 MANUFACTURED BY M/S. HISUN PHARMACEUTICAL INDUSTRIES, GADOON-PAKISTAN

The Federal Inspector of Drugs, Peshawar took sample of Fentos Tablets from the premises of Ms. Hisun Pharmaceutical Industries, Swabi for purpose of test/analysis on Form-3. The Federal Government Analyst has declared following samples of Fentos Tablets as of **"Substandard quality"**. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Report No. & Date
Fentos tablets	M/s. Hisun Pharmaceutical Industries, Gadoon-Pakistan.	047810	599	09-21	09-23	No. IP-6-22-000112 dated 09-09-2022

02. Results of CDL on the basis of which sample under reference has been declared as Adulterated & Substandard are reproduced as under:-

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Identification	The identification test must identify Diclofenac Potassium.	Complies.	USP 43
2.	Dissolution (Acid Stage)	Each unit is not less than 75% (Q).	**Does not comply.**	USP 43
3.	**Assay** Diclofenac Potassium. (Label Claim 50mg/tablet)	90.0% to 110.0%	100.01% Complies.	USP 43

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

2) The sample could not be tested in the initial sixty days due to non-reproducibility of the testing results. Request for additional period (As required under section 22(2) of the Drugs Act 1976) was made to the concerned quarter vide letter No.5-3 (P)/2022-CDL/S-937 (A) dated 22-08-2022.

03. M/s. Hisun Pharmaceutical Industries, Gadoon-Pakistan requested for retesting to Appellate Lab NIH Islamabad.

04. 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 dated 30-11-2022.

05. M/s. Hisun Pharmaceutical Industries, Gadoon-Pakistan submitted that they investigated the matter again by conducting dissolution test on their retained sample of Batch no 599 and the result complies with USP specifications.

06. Federal Government Analyst, CDL, Karachi submitted the OOS investigation form. Remarks of Lab manager are:

"Product tested till stage 2 and it does not complies to specification of stage 2 as well as stage 3 criteria, hence dissolution test results declared as out of specification test."

07. Technical Evaluation of the case:

- The product was declared sub-standard on the basis of dissolution test.
- Ms. Hisun Pharmaceutical Industries, Gadoon-Pakistan submitted test reports.
- Final decision of OOS investigation is "OOS is valid" received from CDL, Karachi.

Procedings and Decision of 333rd Meeting of Registration Board.

- Out of Specification (OOS) investigations and testing records submitted by M/s. HisunPharmaceutical Industries, Gadoon-Pakistan and CDL, DRAP Karachi were presented before Registration Board. The Board deliberated on the OOS investigation and did not agreed with the OOSinvestigation submitted by the firm M/s. Hisun Pharmaceutical Industries, Gadoon-Pakistan.
- The Board did not accede to the firm's request for appellate testing and decided to issue show cause notice to M/s. Hisun Pharmaceutical Industries, Gadoon-Pakistan under Section 42 of the Drugs Act, 1976 and called them for personal hearing before Registration Board in its forthcoming meeting.

CASE NO. 03: MANUFACTURE & SALE OF SUBSTANDARD PARAPALS INFUSION, BATCH NO. LI-100, LI-101 & LI-102, MANUFACTURED BY M/S INVENTOR PHARMA, KARACHI.

The Federal Inspector of Drugs, DRAP inspected the premises of M/s. Sindh Government Hospital, UP Mor, New Karachi on 22-10-2020 wherein, following samples of drugs with apparent discoloration in the solution of Parapals Infusion were taken on Form-3 for the purpose of test/analysis and remaining stock ordered Not to Dispose of on Form-1 under Section 18(1) of the Drugs Act, 1976.

S. No.	Name of Drug	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Reason of Adulterated and Sub-Standard Product (Initial Report)	Reason of Adulterated and Sub-Standard Product (Final Report)
01	Parapals IV Infusion 100ml (R. No. 088360)	088360	**LI-101**	03/2020	03/2022	M/s. Inventor Pharma, Karachi	Deep brown colored solution containing very large fiber particles. Does not Comply.	-Deep brown colored solution- Does not comply. -pH does not comply. -Bacterial sterility- Does not Comply.
02	-do-	-do-	**LI-100**	-do-	-do-	-do-	-do-	Deep brown colored solution- Does not comply. -Bacterial sterility- Does not Comply.
03	-do-	-do-	**LI-102**	-do-	-do-	-do-	-do-	-Deep brown colored solution- Does not comply. -Bacterial sterility- Does not Comply.

02. FID served a number of explanation letters but no reply from the firm is received yet.

03. FID submitted that M/s. Inventor Pharma, Karachi has violated the Section 23(1) (a) (iv) and 23(1) (a) (v) of Drugs Act, 1976 in view of non-positive attitude of the firm towards GMP compliances and product failure ratio. FID recommended that:

i. Registration of the product **Parapals Infusion Reg. No. 088360** may kindly be suspended/cancelled for a certain period being a non-safer drug and all other drugs being manufactured at their premises may kindly be reviewed after detailed panel GMP inspection by the panel.

ii. The names of technical persons may be obtained from Licensing Division, DRAP, Islamabad as firm did not provided the names despite of several letters.

04. A show cause notice has been issued vide office letter of even number dated 05-10-2021 to the firm. No reply has been received so far.

05. Registration Board in its 316th meeting of Registration Board heard the firm's representative and after deliberated the facts of the case in detail decided:

i. Suspension of the Registration of Parapals Infusion (Registration No. 088360) for six months or submission of product development data, root cause analysis along with CAPA; which is later.

ii. Product Specific Inspection shall be conducted by following panel:

a. Mr. Rafeeq Alam
b. Mr. Affan Ali

06. Panel has been revised vide office letter of even number dated 25-11-2023, PSI was conducted dated 10-01-2023. Conclusion of the report reproduced as:

"Based on the above stated facts the panel concluded that failure was because of the improper Nitrogen Gas supply during filling operations which could have caused oxidation resulting blackish of solution. The firm has taken CAPA and manufactured more three trial batches of said product and found satisfactory results of ongoing stability studies thus recommended the resumption of production of Parapals Infusion 1000mg/100ml Registration Number 088360 after taking fresh sample from 1st commercial batch for test/analysis by CDL Karachi on the expense of manufacturer and then firm will sell the product after standard CDL report."

Comments of QA&LT Division:

07. Though the panel recommended the resumption of registration of Parapal Infusion relying upon the RCA & CAPA submitted by the firm. However, it is noted that in RCA the firm only focused on adulteration and did not address the failure of product on the basis of pH and bacterial sterility test. Similarly, CAPA for these two failures were not conducted.

08. Moreover, it is pertinent to mention that in addition to above mentioned 03 batches, other 09 batches (cases are in process) were also drawn from FIDs on different occasions and declared as adulterated and substandard. Following are the details:

S. No.	Name of Drug	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Report No. and date	Remarks of CDL & basis of
1	Parapals IV Infusion 100ml (R. No. 088360)	LI-059	02-2020	02-2022	M/s. Inventor Pharma, Karachi.	No.KQ.251/2020 dated 02-10-2020	Substandard -Deep brown colored solution-Does not comply. -pH-Does not comply. -Bacterial sterility-Does not Comply.
2	Parapals IV Infusion 100ml (R. No. 088360)	LI-058	01-2020	01-2022	-do-	No.KQ.250/2020 (Initial) dated 02-10-2020 No.KQ.250/2020 (Final) dated 20-10-2020	Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply. -Bacterial sterility-Complies
3	Parapals IV Infusion 100ml (R. No. 088360)	LI-115	04-2020	04-2022	-do-	No.KQ.293/2020 dated 07-12-020	Adulterated and Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply. -Bacterial sterility-Complies
4	Parapals IV Infusion 100ml (R. No. 088360)	LI-129	04-2020	04-2022	-do-	No.KQ.292/2020 dated 07-12-020	Adulterated and Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply. -Bacterial sterility-Does not Comply.
5	Parapals IV Infusion 100ml	LI-237	08-2020	08-2022	-do-	No.KQ.261/2020 dated 03-12-2020	Adulterated and Substandard -Deep brown colored solution-Does not comply.

	(R. No. 088360)						- pH-Does not comply. -Bacterial sterility-Does not Comply.
6	Parapals Infusion	LI-051	01-2020	01-2022	-do-	No.KQ.131/2021 dated 30-06-2021	Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply.
7	Parapals Infusion	LI-052	01-2020	01-2022	-do-	No.KQ.132/2021 dated 30-06-2021	Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply.
8	Parapals Infusion	LI-048	01-2020	01-2022	-do-	No.R.KQ.398/2020 dated 09-12-2020	Adulterated and Substandard -Deep brown colored solution-9Does not comply. - pH-Does not comply.
9	Parapals Infusion	LI-050	01-2020	01-2022	-do-	No.R.KQ.399/2020 dated 09-12-2020	Substandard - pH-Does not comply.

Proceedings and Decision of 326th Meeting of Registration Board.

"The Board after considering the facts of the case and after thorough deliberations decided:

i. Suspension of the Registration of Parapals Infusion, Registration No. 088360 of M/s. Inventor Pharma, Karachi for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by panel with satisfactory report; whichever is later.

ii. Resubmission of RCA and CAPA by the firm regarding all quality attributes of product which are declared non-compliant in CDL reports.

iii. To conduct Product Specific Inspection, including but not limited to following TORs, by panel of inspectors/experts to be nominated by Director QA/LT.

(a) To verify the all aspect of RCA and CAPA submitted by firm in the light of test /analysis report of CDL regarding all quality attributes of product which are declared non-compliant.

(b) To verify manufacturing and compliance of sterile product manufacturing in light of Schedule BI and BII of Drugs(L.R.&A.) rules 1976.

Decision letter has been communicated after formal approval of minute of the meeting dated 26th May 2023.

Panel has inspected Ms Inventor Pharma, Karachi, as per 326th RB decision. Panel mentioned the RCA and CAPA conducted by firm as:

"**Brief Overview of the Case:-**

The firm voluntarily taken CAPA after declaration of three batches of substandard and adulterated Parapals Infusion and manufactured more than 250 batches of said product till suspension of the Parapals infusion and found satisfactory results of all ongoing stability batches and market surveillance.

Root Cause Analysis:

The firm has carried out detailed RCA of the failure as per SOP o. QNSOP/015 against the information about Parapals inf. 1000 mg/ 100 ml which was declared as " Adulterated and Substandard " by CDL Karachi in December, 2020 and found following route cause of failure of product.

- Chances of Oxidation in filled vials might be due to improper Nitrogen purging and that had caused change in Physical appearance and in pH of filled vials.

- Chances of adulteration which might be to mal-functioning and improper monitoring of HVAC System at the time of filling.
- Failure on Sterility might be due to improper terminal sterilization process during manufacturing of said batches of Parapals Infusion.

The panel was further briefed about the Risk Assessment studies carried out by them after failure and showed detailed mitigation plan to address such failures in future.

Corrective Action Preventive Action:

It was briefed that they had taken following Correction and Preventive Measures after carrying out RCA & Risk Assessment & mitigation plans.

- Performed Risk Identification, Risk Evaluation, Risk Mitigation calculation and Risk Action Plan.
- Stopped the sale of suspected Batches and recalled from market.
- Replacement and re-calibration of monitoring gauges of nitrogen Gas supply line for purging during filling
- Installed low flow switches to stop the filling operations automatically, when supply pressure drops below 25 PSI.
- Nitrogen gas purging continued into bulk WFI before manufacturing and after filling of solution into the vials.
- The results of stability studies showing stable color & pH during accelerated stability studies and in real time stability studies of Parapals Trail batch# PPV-TR-01 and PPVTR-02 and commercial batches PPV-02, PPV-03 and PPV-04.
- The firm has replaced the older one equipment and installed another terminal Sterilizer and performed thermal mapping scientifically.
- Re-validated entire HVAC system, with changed terminally located HEPA in clean rooms areas.
- Performed DOP/POA test of HEPA Filters.
- Maintained online monitoring of area accordingly i) Particle count, ii) settle plates method.

Panel further mentioned that:

- They also verified the compliance level of GMP in sterile product manufacturing facility, and found satisfactory.
- The panel also verified the testing facility including TOC/ Liquid Particle counter and microbiological testing lab and production capacity of SVP (liquid) vials. The panel reviewed relevant documentation including relevant SOPs, records and found satisfactory as per compliance requirement.
- After in depth evaluation of the above mentioned documents, Risk Assessment, Actions, Post Risk Assessment, interviews of the technical staff, onsite working of the staff and implementation of changes made in response of product failure, the panel concluded that failure in appearance, pH and failure of Bacterial Sterility test found was due to improper nitrogen gas purging during filling operations and efficiency of HV AC System and terminal sterilizer.
- The panel witnessed all changes have been implemented properly they mentioned in attached risk assessment plan and CAP
  A.
- Based on the stated facts and under the given TORs, their RCA, CAPA, GMP and associated Risk Assessment activities have satisfactorily been verified by the panel.

Proceedings and Decision of 333rd Meeting of Registration Board.

The Board after considering the facts of the case and after thorough deliberations decided:

i. To resume the production of Parapals Infusion (100 ml), Reg. No. 088360 of M/s. Inventor Pharma, Karachi on the recommendation of the panel of experts in its report dated 10-01-2023.

ii. The firm shall inform area FID / Additional Director, Karachi regarding resumption of production and start of manufacturing of Parapals Infusion (100ml) Reg. No. 088360.

iii. FID will take samples of 1st, 3rd and 5th commercial batches of Parapals Infusion (100 ml), Reg. No. 088360 of M/s. Inventor Pharma, Karachi for the purpose of test /analysis by CDL, Karachi. The permission for commercial sale is subject to submission of "standard quality" test reports by CDL, Karachi of 1st commercial batch.

iv. Permission of resumption shall be allowed after submission of report in QA&LTDivision by the Additional Director, Karachi.

Case No. 04: IMPORT OF REGISTERED PRODUCTS THROUGH FAKE/FORGED INVOICES BY M/S. BIOCURE PHARMACEUTICALS, LAHORE.

01. Assistant Director (I&E), Lahore vide letter No.5247/2019/DRAP(AD-CD) (I&E) dated 15-04-2019 informed that Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi has asked for the verification of genuineness of following ADC invoices;

Sr. No	Invoice No. & Date	Diary No. & date	Dispatch No. & Date
1	SBF/EXP/23-2019, dated 21-02-2019	4699/2019 DRAP dated 15-03-2019	3769/2019-DRAP, dated 19-03-2019
2	SBF/EXP/24-2018, dated 15-03-2018	4569 dated 26-03-2018	4451/2018-DRAP, dated 29-03-2018
3	SBF/EXP/28-2017, dated 29-03-2017	5982 dated 27-04-2017	5647/2017-DRAP, dated 28-04-2017
4	SBF/EXP/127-2015, dated 28-10-2015	13579 dated 23-11-2015	18835/2015-DRAP, dated 26-11-2015
5	SBF/EXP/128-2016, dated 27-12-2016	1524 dated 26-01-2017	1396/2017-DRAP, dated 27-01-2017

02. AD (I&E), DRAP, Lahore further informed that the genuineness of the endorsement of said invoices is not verified from the office record. In response to the submission of AD (I&E), DRAP, Lahore the division of QA&LT directed the Area FID vide letter F. No.13-125/2019-(QC) dated 16-05-2019 to investigate the matter and after completing all the legal formalities, submit a comprehensive report including all the requisite documents, if any, on priority basis for consideration of the Board.

03. Area Federal Inspector of Drugs Lahore vide letter No.7011/2021-DRAP (L-IV) dated 07-05-2021 submitted the complete investigation report and the reply of accused as under:

S.No.	Invoice No & Date	Diary No. & date	Dispatch No, & Date
1	SBF/EXP/23-2019, dated 21-02-2019	4699/2019 DRAP dated 15-03-2019	3769/2019-DRAP, dated 19-03-2019
2	SBF/EXP/24-2018, dated 15-03-2018	4569 dated 26-03-2018	4451/2018-DRAP, dated 29-03-2018
3	SBF/EXP/28-2017, dated 29-03-2017	5982 dated 27-04-2017	5647/2017-DRAP, dated 28-04-2017
4	SBF/EXP/127-2015, dated 28-10-2015	13579 dated 23-11-2015	18835/2015-DRAP, dated 26-11-2015
5	SBF/EXP/128-2016, dated 27-12-2016	1524 dated 26-01-2017	1396/2017-DRAP, dated 27-01-2017

2 Letter No. 12040/2019-DRAP (L-VI) dated, 17-09-2019, was sent from this office to M/s. Biocure Pharmaceuticals, to explain their position in this regard (copy attached annex-9).

3 Reply received from M/s. Biocure Pharmaceuticals, Jail Road, Lahore vide letter No. Nil, dated Nil received office on 02-10-2019 (copy attached annex-10), wherein they have informed that after coming to know of the above they launched FIR against the clearing agent, whom they had hired some time ago .The CEO of the firm further informed that he was shaken after knowing about this matter which caused severe tension, heart attack and cardiogenic shock. He has further requested that he may be granted relief on humanitarian basis. Previous import history of the firm as per this office record showing clearance certificates obtained from this office previously is also. But as per available record of this office the above said invoices were not cleared by this office.

4 The available data of this office reveals that the firm did not get prior clearance to import their products Eridoksin Registration No. 059185 and Roxine 25% Registration No. 059186 which is the violation of the Drugs Act 1976/DRAP Act 2012, so, it is recommended that the registration of the drugs / product in question may be suspended or cancelled or any other action may be taken as deemed fit by the Competent Authorities.

Submitted for information and further necessary action please."

04. Area FID Lahore in the above-mentioned report has recommended the cancellation/suspension of registration of products namely Eridoksin powder containing Erythromycin 40mg and Doxycycline 20mg (Reg. No. 059185) and Roxine 25% oral solution containing Enrofloxacin 250g (Reg. No. 059186) or any other action as may deem fit by the Board.

05. The Board in its 312th meeting decided to issue show cause notice to firm for cancellation/suspension of their registered product.

06. In compliance to the decision of 312th meeting of the Registration Board, the firm was issued show cause notice vide F.No.03-33/2021-QC (312-RB) dated 28-10-2021. Till date no reply has been received from the firm.

07. The representatives of the firm are called before the Board for personal hearing.

Proceedings and Decision of 313th meeting:

08. Jawad Ahmed (CEO) of M/s. Biocure Pharmaceuticals, Suite No. 211, 2nd Floor Khaleej Town, 38-A, Jail Road Lahore appeared before the Board and informed the Board that he had hired a clearing agent namely Muhammad Sadiq S/o Abdul Aziz R/o House No. 49-A, Street No. 139-C, Ittefaq street, Ghulam road, Ichhra Lahore who was responsible for submitting fake invoices to the custom authorities. Moreover, Mr. Jawad Ahmed also informed the Board that he was unaware of these illegal activities being carried out by his clearing agent and he also had lodged FIR against that clearing agent in Litton road Police Station Lahore.

09. The Board after thorugh deliberations, considering the facts of the case and submission of CEO of M/s. Biocure Pharmceuticals Lahore decided as under:

i. Suspend the Registration of the products namely Eridoksin Powder (Reg. No. 059185) and Roxine 25% oral solution (Reg. No. 059186) for (06) months.
ii. The division of QA&LT will conduct a detailed investigation of the matter and submit a comprehensive report before the Board within (02) months.

10. In the light of the decision of Registration Board, the accused were issued a letter for suspension of their products vide letter F. No. 03-43/2021-QC (313-RB) dated 16-12-2021. Moreover, brief facts of the case are given as under:

1) Assistant Director (I&E), Lahore vide letter No.5247/2019/DRAP(AD-CD)(I&E) dated 15-04-2019 informed that Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi has asked for the verification of genuineness of ADC invoices as mentioned in table of para 01.
2) The division of QA&LT directed the Area FID vide letter F. No.13-125/2019-(QC) dated 16-05-2019 to investigate the matter and submit a comprehensive report of the matter.
3) Area FID Lahore informed that the invoices provided by the Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi are forged and the firm did not get prior clearance to import their products and recommended that the registration of the drugs / product in question may be suspended or cancelled.
4) The Registration Board in its 312th meeting decided to issue Show cause notice and personal hearing to the management of M/s. Biocure Pharmaceuticals Lahore.
5) Jawad Ahmed (CEO) of M/s. Biocure Pharmaceuticals of the firm appeared before the Board in its 312th meeting and submitted that he had hired a clearing agent namely Muhammad Sadiq S/o Abdul Aziz R/o House No. 49-A, Street No. 139-C, Ittefaq street, Ghulam road, Ichhra Lahore and the fake invoices were submitted by him. The said person is not traceable and Jawad Ahmad (CRO) of M/s. Biocure Pharmaceuticals Lahore had lodged FIR against that person in Litton road Police Station Lahore. A Copy of FIR is also submitted by the CEO of M/s. Biocure Pharmaceuticals Lahore.
6) The invoices provided by Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi are dated 26-11-2015, 27-01-2017, 28-04-2017, 29-03-2018 and 19-03-2019 in her letter dated 15-04-2019 whereas the accused had lodged the FIR against his clearing agent on 22-06-2019.

10. The case has been deferred due to paucity of time in 320th meeting.

11. The Registration Board deferred the case in 321st meeting for further deliberation in next meeting.

Proceedings and Decision of 324th Meeting of Registration Board:

12. Registration Board after discussion, considering the facts of the case decided as:

"Case is forwarded to legal division for opinion in said case."

13. In the light of decision of 324th meeting of the Registration Board, the matter was forwarded to the division of Legal Affairs DRAP Islamabad for their opinion in the subject matter. Reply of the division is given as under:

"Reference to the preparas and facts submitted on the file, this Division is opined that if the authority letter had given to the clearing agent and he submitted all invoices, whether fake or forged, under agency agreement by representing the principle then the vicarious liability will also be on the owner of the firm. Moreover, as per available facts, owner of the firm never presented his agency agreement or Authority letter with DRAP and he merely lodged FIR against the agent in order to avoid prosecution by DRAP. Therefore, FIR/prosecution may be lodged against the owner of the firm immediately."

Proceedings and Decision of 333rd Meeting of Registration Board:

- Response of the Division of Legal Affairs DRAP was placed before the Board and was deliberated in depth. The Board was apprised that the firm was served Showcause notice No. F.No.03-33/2021-QC (312-RB) dated 28-10-202 under Section 42 of the Drugs Act, 1976. The firm was offered personal hearing in 313th meeting of Registration Board.

- Representative of Ministry of Law & Justice, Islamabad opined that permission to lodge FIR/Prosecution on the basis of submission of documents to the customs for clearance of stocks does not fall under the jurisdiction of the Registration Board.

- Board keeping in view legal opinion of Member from Ministry of Law & Justice, investigation report and recommendations of area Federal Inspector of Drugs Lahore and stance of division of QA&LT DRAP decided to cancel registration of following drugs registered in the name of M/s. Biocure Pharmaceuticals, Jail Road, Lahore:
  i. Eridoksin powder (Erythromycin 40mg and Doxycycline 20mg) Registration No. 059185.
  ii. Roxine 25% oral solution (Enrofloxacin 250g) Registration No. 059186.

- A reference shall be sent to Import & Vet Section & RRR Section for record.

Case No. 05: SUBSTANDARD GENTAMYCIN EAR DROPS MANUFACTURED BY M/S. AMROS PHARMA KARACHI – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/723 dated 22-02-2022 forwarded the case of manufacturing of Substandard Gentamycin 10ml Ear Drops Manufactured by M/s. Amros Pharmaceuticals Karachi. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of main store of DHO Office Islamabad drew samples of Gentamycin 10ml Ear drops B. No. EAM-011 manufactured by M/s. Amros Pharmaceuticals Karachi for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Gentamycin Ear drops as "Substandard" on the basis of pH.
iii. M/s. Amros Pharmaceuticals Karachi requested to challenge the results of DTL test report in NIH Islamabad. The appellate laboratory, NIH Islamabad also declared the Gentamycin 10ml ear drops as of "substandard" quality on the basis of pH and volume.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

> *"The Board was briefed about the facts of the case as per record by Secretary. The Board was also informed that the nominated accused did not appear. The Board considered the facts available on record and after discussion decided to refer the case to Drug Registration Board for cancellation of drug registration of i.e. Ear Drops Gentamycin manufactured by M/s. Amros Pharmaceuticals Karachi after fulfilment of all legal/codal formalities in this regard."*

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of Gentamycin 10ml Ear Drops, Reg. No. 019368 manufactured by M/s. Amros pharmaceuticals Karachi.

Proceedings and Decision of 320th meeting:

04. The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

05. Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Amros pharmaceuticals Karachi for manufacturing and sale of substandard "Gentamycin 10ml Ear drops B. No. EAM-011" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

06. In the light of decision of decision of Board, the accused were issued show cause notice vide letter F. No. 03-45/2022-QC(321-RB) dated 15-11-2022 with subsequent reminders on 06-01-2023 and 13-11-2023. Till date no reply has been received from the firm.

Proceedings and Decision of 333rd Meeting of Registration Board:

07. The matter was deliberated in depth and Board showed grave concerns regarding attitude of firm towards the matter at hand and decided as under:

i. Suspension of the Registration of Gentamycin Ear Drops (Registration No. 019368) manufactured by M/s. Amros Pharmaceuticals Karachi for six months and submission of product development data, root cause analysis along with CAPA.
ii. Product Specific Inspection shall be conducted by panel recommended by the Director QA&LT.
iii. The Board further decided to direct the DRAP office Karachi to not to accede with the request(s) of M/s. Amros Pharmaceuticals Karachi for clearance of Gentamycin API during the suspension period.

Case No. 06: SUBSTANDARD MENTIN FORTE TABLET MANUFACTURED BY M/S. UNEXO LABS LAHORE – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/722 dated 22-02-2022 forwarded the case of manufacturing of Substandard Mentin Forte Tablet Batch No. MT80 Manufactured by M/s. Unexo Labs (Pvt.) Ltd., Lahore. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of District Population Welfare Office G-9 markaz Islamabad drew samples of Mentin Forte 625mg tablet Batch No. MT80 manufactured by M/s. Unexo Labs Lahore for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Mentin forte tablet as "Substandard" on the basis of assay.
iii. The accused were called before Quality Control Board Islamabad in its 50th meeting but no one appeared before the Board.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

> *"The nominated accused did not appear before the Board. The Board considered the facts available on record and decided to refer the case to the Drug Registration Board for cancellation of registration of drug i.e. Tab Mentin Forte (Co Amoxiclav) of M/s Unexolabs, Lahore after fulfillment of all legal formalities in this regard."*

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of tablet Mentin Forte, Reg. No. 023923 manufactured by M/s. Unexolabs Lahore.

Proceedings and Decision of 320th meeting:

04. The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

05. Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Unexolabs Lahore for manufacturing and sale of Substandard product "Mentin Forte Tablet Batch No. MT80" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

06. In the light of decision of decision of Board, the accused were issued showcause notice vide letter F. No. 03-45/2022-QC(321-RB) dated 15-11-2022. In response to said showcause, M/s. Unexo Laboratories Lahore vide letter Ref. UL/Mentin Forte/MT80 dated 29-11-2022 replied as under:

> *"Dear Sir,*
> *With reference to your letter no.* ***F. No. 3-45/2022-QC (321-RB),*** *dated 15th November 2022 and subject matter. We would like to bring to your kind attention the following points.*
> *1. The Inspector of Drugs ICT, Islamabad sampled the product* ***Tab. Mentin Forte (Batch MT80)*** *from the Main Stores District Population Welfare office, Islamabad, on* ***24.07.2017*** *for the purpose of test and analysis.*
> *The sample was received by DTL, Rawalpindi on* ***26th July 2017.***
> *The reporting date on the* ***DTL Report No.TRA. 01-07001941/DTL is 22nd November 2017.*** *This is a period of* ***4 months*** *from receipt of sample by DTL and its analysis. Drug Act 1976 stipulates a time of* ***60 days*** *within which the DTL has to report the results of the sample analysis. This makes the DTL Report* ***No.TRA. 01-07001941/DTL time barred.***
> *2. For the sake of argument if we consider the letter No.* ***SMR49/DTL/RWP/2017, dated 16.08.2017*** *sent to us by* ***DTL, Rawalpindi,*** *intimating to send the method of analysis of Mentin forte Tablet.*
> *We sent the required information to DTL, Rawalpindi via letter No.* ***UL/786/2017/Mentin****, dated* ***25.08.2017*** *by courier.*
> *The maximum time a letter sent by courier takes* ***4 days*** *to reach the destination. So assuming the letter reached DTL by* ***30.08.2017.***

*The DTL, Rawalpindi should had conducted the test at the maximum by **29th October 2017**. But in this case the DTL Report No. **TRA. 01-07001941/DTL** is dated **22nd November 2017**. That is also outside the stipulated time limit of 60 days as required by Drug Act 1976, making the DTL Report No. **TRA. 01-07001941/DTL time barred.***

3. We were not given the opportunity to request for retesting for our product Mentin Forte Tablet (Batch No. MT-80) from appellate laboratory, as per Drugs Act 1976 and the law/rules framed thereunder. Reason being that we were not furnished with the required documentation to completely scrutinize the case before requesting for retest. We were furnished with the required documentation in parts by the Drug Inspector ICT, Islamabad after our repeated requests.

Still to date we have not been furnished with the copy of invoice/warranty from the store keeper of main store, District Population Welfare office, Islamabad as proof of purchase.

*4. We repeatedly informed the Inspector of Drugs, ICT, Islamabad, that **M/S. Mediwise Pharma is not our authorized distributor**, who supplied the Mentin Forte (Batch MT-80) to District Population Welfare Office.*

*The storage conditions of the said Distributor **M/S. Mediwise** are not known, as well as the storage conditions of District Population Welfare office, Islamabad, Improper storage affects the stability of the product.*

Subsequently, we cannot be held responsible for the condition of the product supplied by an unauthorized distributor with unknown credentials and storage conditions.

In the light of the above facts, it is kindly requested for a considerate look at this case and to dismiss it.

That our such request is in line with our rights of fair defense and in the interest of justice as well as to ensure the adherence and compliance with the legal mandates and stipulations.

Kindly find attached the copies of correspondence with Inspector of Drugs ICT, Islamabad and DTL, Rawalpindi."

07. Reply of the firm was communicated to Secretary QCB Islamabad vide letter F. No. 03-14/2022-QC dated 13-01-2023. Secretary QCB Islamabad vide letter F. No. 18(1)-QCB/ICT/2012 dated 27-11-2023 responded to the queries raised by firm as under:

"[…] 2. It is pertinent to mention here that the Tab. Mentin Forte Batch No. MT80 manufactured by M/s Unexo Labs (Pvt) Ltd, was declared Sub-standard by the DTL. Furthermore, the sample was drawn from main stores/warehouse of District Population Welfare Office, Islamabad.

3. The response of queries is written as;

i. DTL had requested for time extension for testing of samples, that was issued accordingly by the Quality Control Board, Islamabad.

ii. No such request regarding appellate testing was ever received by this office or Quality Control Board;

iii. Copy of invoice from District Population Welfare Office is attached.

iv. The complete supply chain evidence of Mentin Forte Tablet, Batch No. MT80 is attached herewith."

Proceedings and Decision of 333rd Meeting of Registration Board:

08. The matter was presented before and was thoroughly deliberated by the Board. Keeping in view the stance submitted by firm and reply of Secretary QCB Islamabad the Board decided as under:

i. Call the firm before the Board for a chance of personal hearing.

ii. Invite the Secretary QCB Islamabad in forthcoming meeting of the Board to provide assistance to Board in the matter at hand.

Item No. IV. Additional Agenda

Agenda of Evaluator PEC-II

Case No.01 Registration applications as per decision of Authority regarding Isoflurane and Sevoflurane products.

- **Registration applications of Finished Drug Product Import**

1.	**Name, address of Applicant / Importer**	**M/s RA Health Care (SMC-Pvt.) Ltd.**
	Details of Drug Sale License of importer	**License No:0312** **Address:** 2nd floor Building No. 50 Mir Arcade Mini Commercial Phase 7, Bahria Town Rawalpindi **Validity:** 11-01-2022 **Status:** License to sell drugs as a Distributor Firm has also submitted receipt of application of renewal of DSL applied to Directorate of Drugs Control Punjab (Reference no. 374-19674461-2022)
	Name and address of marketing authorization holder (abroad)	M/s Baxter Healthcare Corporation, Route 3-Km144.2, Guayama, Puerto, Rico 00784 (USA)
	Name, address of manufacturer(s)	M/s Baxter Healthcare Corporation, 1 Baxter Parkway, Deerfield, IL 60015 United Sates of America.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. EUDP-C5PJ) valid till 21-02-2023 issued by US FDA for Sevoflurane Inhalant 250ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. **The name of importing country on CoPP is mentioned as Pakistan.** Applicant of COPP is M/s Baxter Healthcare Corporation, 25212 W II Route 120, Round Lake IL 60073 , USA.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized letter of authorisation from M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China. The letter authorises **M/s IBL Health Care Ltd.** ne IBL Centre, 2nd Floor, Plot No 01, Block 7 & 8 Dehli Merchantile Cooperative Housing Society (DMCHS Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi to submit application to DRAp for registration approval in Pakistan. The authorization letter is issued dated 10-01-2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Tracking ID and date of submission	Dy. No. 23134 dated 16-08-2022
	Details of fee submitted	PKR 150000/- 20-07-2022
	The proposed proprietary name / brand name	**Sevoflurane**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sevoflurane …. 250ml (1ml/ml)
	Pharmaceutical form of applied drug	Liquid for inhalation
	Pharmacotherapeutic Group of (API)	Inhalation Anaesthesia
	Reference to Finished product specifications	USP
	Proposed Pack size	250ml
	Proposed unit price	--
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	Sevof liquid for inhalation 250ml of M/s Getz (Reg.# 103781)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	1. M/s Baxter Healthcare Corporation, Route 3-Km144.2, Guayama, Puerto, Rico 00784 (USA). 2. M/s Halocarbon Products Corp. 1100 Dittman Court North Augusta, SC 29841 USA
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has comparative studies against Ultane liquid for Inhalation of M/s Abbvie Inc.

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Aluminium Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% The real time stability study data for 3 batches is for 60 months only.
Evaluation by PEC: • Firm has not submitted process validation protocol, declaring that since the manufacturing process for Sevoflurane drug product consists only of packaging of the drug substance, process validation is not applicable.		
Decision: Approved as per policy of inspection of manufacturer anbroad.		
2.	**Name, address of Applicant / Importer**	**M/s IBL Health Care Ltd.**
	Details of Drug Sale License of importer	**License No:0312** **Address:** Section-A, 2nd Floor, Plot No 01, Block 7 & 8 Dehli Merchantile Cooperative Housing Society (DMCHS Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore, **Validity:** 07-04-2024 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 20235057) valid till 13-14-2025 issued by Shandong Provincial Drug Administration. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection of once a year. **The name of importing countries on CoPP include Pakistan.**
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized letter of authorisation from M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China. The letter authorises **M/s IBL Health Care Ltd.** ne IBL Centre, 2nd Floor, Plot No 01, Block 7 & 8 Dehli Merchantile Cooperative Housing Society (DMCHS Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi to submit application to DRAp for registration approval in Pakistan. The authorization letter is issued dated 10-01-2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Tracking ID and date of submission	PP6-RH5-T19P dated 29-11-2023
	Details of fee submitted	PKR 150000/- 01-11-2023
	The proposed proprietary name / brand name	**SEVOLIFE 250ml for Inhalation**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml bottle contains: Sevoflurane ….. 100%.
	Pharmaceutical form of applied drug	Liquid for inhalation
	Pharmacotherapeutic Group of (API)	General Anaesthesia
	Reference to Finished product specifications	USP
	Proposed Pack size	250ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved.
	For generic drugs (me-too status)	Sevof liquid for inhalation 250ml of M/s Getz (Reg.# 103781)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shandong New Time Pharmaceutical Co., Ltd., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has comparative studies against Ultane liquid for Inhalation of M/s Abbvie Inc.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type III amber glass bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% The real time stability study data for 3 batches is for 36 months only.

Evaluation by PEC:

Section no.	Observations	Firm's response
3.2.P.8.3	• Justification shall be submitted for Not performing test of all the Organic Impurities, as recommended by USP monograph during drug product stability studies.	

Decision: Deferred for submission of reply to the above cited shortcoming.

- **Applications of Local Manufacturing.**

3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Allmed (Pvt.) Ltd. Plot # 590, Sunder Industrial Estate, Lahore-Pakistan**
	Name, address of Manufacturing site.	M/s Allmed (Pvt.) Ltd. Plot # 590, Sunder Industrial Estate, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate # F.11-6/2021-DRAP-65, dated 25-08-2021 based on inspection conducted on 10-08-2021.
	Evidence of approval of manufacturing facility	Liquid Solution for inhalation (General), approval granted by Secretary (Central Licensing Board) vide letter No. F. 1-20/2005-Lic(Vol-II) dated18-05-2022.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Application ID & Date of submission	3DN-G1X-2LHJ dated 13-12-2023
	Details of fee submitted	Rs.30,000/- dated 03-11-2023
	The proposed proprietary name / brand name	Isoflo 100ml Liquid for Inhalation
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Isoflurane-------- 100ml
	Pharmacotherapeutic Group of (API)	Anaesthetic general
	Pharmaceutical form of applied drug	Liquid for inhalation
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Forane 100ml Liquid for Inhalation by Baxter Healthcare Corp USA approved by US FDA
	For generic drugs (me-too status)	Restane100ml Liquid for Inhalation of M/s Allied Distributors Reg. # 044867
	Name and address of API manufacturer.	M/s SHANDONG NEW TIME PHARMACEUTICAL CO., LTD., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone II
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence of their product against the Restane Inhalational Solution.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s SHANDONG NEW TIME PHARMACEUTICAL CO., LTD., No.1, North Outer Ring Road, Feixian County, Shandong Province, China
API Lot No.	597201001
Description of Pack (Container closure system)	Amber Glass bottle of Type III
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-081	RD-082	RD-083
Batch Size	160 bottles	160 bottles	160 bottles
Manufacturing Date	06-2022	06-2022	06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML (Certificate No. Lu 20160193) valid up to 03-12-2025 issued by Shandong Province Drug Administration, China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section no.	Observation	Firm's response
3.2.S.3	IR absorption spectra of Isoflurane, performed by M/s Allmed Pvt. Ltd. shall be submitted.	
3.2.S.4	• Drug substance specifications submitted form M.s Allmed Pvt. Ltd. shall be signed and stamped. • Submitted drug substance specifications form M/s Allmed does not include test of "Organic Impurities" as recommended by USP monograph of "Isoflurane". Justification shall be submitted in this regard. • As per USP monograph of Isoflurane the percentage of Isoflurane in the sample Assay has to be calculated Using the results from the test for *Organic Impurities*. Justification shall be submitted how the Assay resultscould be inferred without performance of test of Organic impurities as per recommendations of USP Monograph. • Reference shall be submitted for the submitted analytical procedure for Assay test. • Analytical method verification studies for the Test of Organic Impurities shall be submitted.	
3.2.S.5	COA of reference/working standard used by M/s Allmed for the drug substance analysis shall be submitted.	

	3.2.S.7	Drug substance stability data shall be submitted as per Zone IVA.		
	3.2.P.2.2.1	Justification shall be submitted for not performing test of organic Impurities in the Pharmaceutical Equivalence studies since as per USP monograph it is required for inferring the Assay results. Details of procurement of the reference product shall be submitted.		
	3.2.P.2.2.3	• Justification shall be submitted for the proposed Assay limits of 98% - 102%. • Details of protective measures adopted for the Occupational Hazards during processing and handling of the drug product shall be submitted.		
	3.2.P.5	➢ Justification shall be submitted forfollowing: • Proposed Assay limits of 98% - 102%. • Not including test of Organic Impurities, Non-volatile residue, Chlorides & Aciditiy or Alkalinity as recommended by USP monograph. ➢ As per USP monograph of Isoflurane the percentage of Isoflurane in the sample Assay has to be calculated Using the results from the test for *Organic Impurities*. Justification shall be submitted how the Assay results could be inferred without performance of test of Organic impurities as per recommendations of USP Monograph. ➢ Reference shall be submitted for the proposed analytical procedure for Assay test.		
	3.2.S.6	COA of reference/working standard used by M/s Allmed for the drug product analysis shall be submitted.		
	3.2.P.8.3	➢ Documents for the procurement of API with approval from DRAP shall be submitted. ➢ Justification shall be submitted for Not performing test of Organic Impurities, Non-volatile residue, Chlorides & Aciditiy or Alkalinity as recommended by USP monograph during drug product stability studies.		
	2.3.R.1.1	➢ As per submitted batch manufacturing record, the filling and sealing of drug product bottles was done manually. Justification shall be submitted for the manual operations of filling and sealing considering the occupational Hazards associated with the applied formulation.		
	--	Details shall be submitted for the systems and equipments installed in the "Liquid Solution for inhalation (General) section" for the processing and handling of applied drug product.		
Decision: Deferred for submission of reply to the above cited shortcoming.				

Agenda of Evaluator PEC-III

Case No. 01 Registration applications of short molecules as per 165th meeting of Authority

4.	**Name, address of Applicant / Importer**	**M/s Mehran International 498-C, Feroz Shah Mehta Road, Karachi**
	Details of Drug Sale License of importer	**License No:** DHOEastK(Drugs)/1192 **Address:** 498-C, Feroz Shah Mehta Road, Karachi **Address of Godown:** NA **Validity:** 01-08-2023. **Status:** Drug License by way of wholesale Firm has submitted application dated 02-08-2023 along with 5000 fee for renewal of DSL
	Name and address of marketing authorization holder (abroad)	Xi'an Libang Pharmaceutical Co., Ltd. No. 22, Keji Yi Road, Xi'an Hi-Tech Industrial Development Zone, Xi'an City, China.
	Name, address of manufacturer(s)	Xi'an Libang Pharmaceutical Co., Ltd. No. 22, Keji Yi Road, Xi'an Hi-Tech Industrial Development Zone, Xi'an City, China.
	Name of exporting country	China.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP (20230010) dated 24-08-2023 for Bio-Fol MCT/LCT 1% Injection 200mg/20ml. The certificate confirmsthe free sale status of the product along with GMP status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted Contract of Agency between Ningbo Voice Biochemic Co Ltd, Xi'an Libang Pharmaceutical Co and Mehran International dated 20-09-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Tracking ID and date of submission	HHN-DVP-GJYA: 13-12-2023
	Details of fee submitted	PKR 150,000/-: 03-11-2023
	The proposed proprietary name / brand name	**BIO-FOL MCT/LCT 1% Injection 200mg/20ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 20ml ampoule contains: Propofol 200mg
	Pharmaceutical form of applied drug	White, aqueous and isotonic emulsion in glass ampoule
	Pharmacotherapeutic Group of (API)	Anaesthetic
	Reference to Finished product specifications	USP

	Proposed Pack size	5 ampoules / tray, 5 trays / box
	Proposed unit price	No submitted by the firm
	The status in reference regulatory authorities	DIPRIVAN® (propofol injectable emulsion), for intravenous use 10mg/ml **(USFDA** Approved).
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Xi`an Libang Pharmaceutical Co., Ltd. Baoji API Plant West-door outside, Guo Town, Chencang District, Baoji city, 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 (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30ºC / 65% RH. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against Propofol 10 mg/ml of M/s Abbott Laboratories
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Glass ampoule
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.
Evaluation by PEC:		

Sr. No	Observations communicated	Response by the firm
1.	Evidence of me-too status in 20ml ampoule form.	We are mentioning below the evidence of Me-Too Status in 20ml Form 01) DIPRIVAN 1% BY ICI PAKISTAN LIMITED 5AMPX20ML 02) FRESOFOL 1% BY MEDIPAK 5AMPX20ML 03) POFOL 1% BY AKHAI 1AMPX20ML
Decision: Approved as per policy of inspection of manufacturer abroad.		

- **Applications of Local Manufacturing**

5.	Name, address of Applicant / Marketing Authorization Holder	**M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 13-01-2022 specifying sachet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID: LLE-ZZV-UWH1 dated 14-12-2023
	Details of fee submitted	PKR 30,000/- Dated 21-11-2023
	The proposed proprietary name / brand name	**KOLSET Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Cholestyramine. ...4g
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Other Antilipemics / Lipid-regulating drug
	Reference to Finished product specifications	USP
	Proposed Pack size	50’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Questran 4g/sachet Powder for Oral Suspension (MHRA Approved)
	For generic drugs (me-too status)	Could not be confirmed
	Name and address of API manufacturer.	Phaex Polymers Private Limited Plot F10, MIDC Murbod Thane 421401 Maharasthra India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information

		related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 72 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Questran 4g sachet
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Phaex Polymers Private Limited Plot F10, MIDC Murbod Thane 421401 Maharasthra India		
API Lot No.			
Description of Pack (Container closure system)	Aluminium sachet		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	069NS01	069NS02	069NS03
Batch Size	500 Sachet	500 Sachet	500 Sachet
Manufacturing Date	04-2023	04-2023	04-2023

Date of Initiation	24-04-2023	24-04-2023	24-04-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by FDA Mahrashtra India valid till 03-03-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import issued dated 31-05-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Evidence of me-too status, since you hve selected the product status as generic product and also submitted 30,000 fee as a generic product.	
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
3.	Submit COA of the relevant batch of API used in the development for three stability batches in section 3.2.S.4.4.	
4.	Specify why module 3.2.S and DMF are separately submitted as different documents	
5.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical studies are conducted	
6.	Justify why in vitro binding and dissolution studies are not conducted under the product development, since both these studies are recommended in the public assessment reports	
7.	Submit clearance certificate as evidence of import of API	

Decision: Deferred for submission of reply to the above cited shortcoming.

SALATEEN WASEEM PHILIP
DEPUTY DIRECTOR (PE&R)

6.	**Import Molecules**	
	Name, address of Applicant / Importer	**M/s Highsea Pharmaceutica** **Address: 2nd floor, 39 Commercial, Cavalry Ground, Lahore Cantt., Pakistan.**
	Details of Drug Sale License of importer	License No: 05-352-0058-100282D Address: 2nd foor, 39 Commercial, Cavalry Ground, Lahore Cantt, Pakistan. Address of Godown: NA Validity: 01.12.2027 Status: **VALID**
	Name and address of marketing authorization holder (abroad)	**FUGIAN HIGHSEA UNITED PHARMACEUTICAL CO. LTD.** Address: No. 15, Zone D, Ming Xi County, Fujian. **China.**
	Name, address of manufacturer(s)	**FUGIAN HIGHSEA UNITED PHARMACEUTICAL CO. LTD.** Address: No. 15, Zone D, Ming Xi County, Fujian. **China.**
	Name of exporting country	**China.**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Photocopy submitted by firm** **Date of Legalization:** not provided • **CoPP:** Firm has submitted photocopy of CoPP certificate (No.20220009) dated 16-06-202 issued by Fujian Medical Products Administration, China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 15-06-2024 • **GMP:** The firm has also submitted photocopy of Drug Production License (duplicate) issued by Fujian Province Medical Products Administration.
	Details of letter of authorization / sole agency agreement	The agency agreement submitted doesn't mention anything regarding sole agency agreement or authorization / declaration of applicant in Pakistan to process for registration of drug product 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. No. 37508 Dated: 22nd December 2023
	Details of fee submitted	PKR 150000/-: 27th September 2023 Slip # 3281403637
	The proposed proprietary name / brand name	**Seaflourane 250 ml Liquid for inhalation**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml contains Sevoflurane..... % w/v
	Pharmaceutical form of applied drug	Volatile Liquid for Inhalation
	Pharmacotherapeutic Group of (API)	General Anesthetic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	250ml per bottle
	Proposed unit price	PKR 29950 per 250 ml bottle
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Product name:** Sevoflo Solution **Importer:** Allmed (Pvt.) Ltd **Reg. #** 114071
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	**FUGIAN HIGHSEA UNITED PHARMACEUTICAL CO. LTD.** Address: No. 15, Zone D, Ming Xi County, Fujian. **China.**
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C / RH 75% ± 5% for 06 months. **Real time:** 25ºC ± 2°C / RH 65% ± 5% for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** Sevofurane Solution for inhalation **Manufacturer**: Maruishi Pharmaceutical Co. Ltd. Japan.

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Brown Soda Lime glass bottle with aluminum cap lined with LDPE.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 09 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 65% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 25ºC ±2ºC **Relative Humidity:** 65% ± 5%.

Evaluation by PEC:

During initial scrutiny, following observations / shortcomings were observed:

Section	Observations
1.3.4	• Please submit legalized GMP certificate and Certificate of Pharmaceutical product. • Please submit letter of authorization issued by Manufacturer abroad declaring Highsea Pharmaceutica Lahore as a sole distributor for the drug products mentioned in it.
3.2.P.8	• Please submit complete stability data for long term storage conditions as per climatic conditions of Pakistan for the claimed shelf life of drug product.

Decision: Deferred for submission of reply to the above cited shortcoming.

7.	**Import Molecules**	
	Name, address of Applicant / Importer	**M/s AMB HK ENTERPRISES Pvt Ltd. Pakistan** ***(Importer)*** **Head office:** 60-K, Commercial Phase-I, DHA Contonement Punjab
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore **Address of Godown:** NA **Validity:** 24-02-2023. **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad) / **Exporter.**	**LIAONING HONGYUAN PHARMACEUTICAL CO. LTD.** Floor 1, Building 2, Standardized Workshop, No. 18 Shennong Dajie, Ben Xi High-tech Industrial Development Zone, Liao Ning Province **China.**
	Name, address of manufacturer(s)	**Hebei Shanmushi Pharmaceutical Co. Ltd.** No. 123, Zhayuan Road, Zhao County, Shijiazhuang City, Hebei Province **China.**
	Name of exporting country	**China.**

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Photocopy submitted by firm</u>** **Date of Legalization:** not provided • **CoPP:** Firm has submitted photocopy of CoPP certificate (No.20220316) dated 23-08-2022 issued by Hebei Province Drug Administration, China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 15-06-2024 • **GMP:** The firm has also submitted photocopy of Drug Production License issued by Hebei Food & Drug Administration, China.
	Details of letter of authorization / sole agency agreement	Sole Agreement submitted by firm. **Contract #** SMS-HY-20220827 **Dated:** 27th August 2022 **M/s AMB HK ENTERPRISES Pvt Ltd** declared as sole / exclusive agent 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. No. 30344 Dated: 26th October 2023
	Details of fee submitted	PKR 150000/-: 05-10-2022 Slip # 0672569338
	The proposed proprietary name / brand name	**Savotane 250 ml Liquid for inhalation**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml contains Sevoflurane..... % w/v
	Pharmaceutical form of applied drug	Volatile Liquid for Inhalation
	Pharmacotherapeutic Group of (API)	General Anesthetic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	250ml per bottle
	Proposed unit price	PKR 7100 per 250 ml bottle
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	**Product name:** Sevoflo Solution **Importer:** Allmed (Pvt.) Ltd **Reg. #** 114071
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 substancemanufacturer	**Hebei Shanmushi Pharmaceutical Co. Ltd.** No. 123, Zhayuan Road, Zhao County, Shijiazhuang City,Hebei Province **China.**
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stabilitystudies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C / RH 75% ± 5% for 06 months. **Real time:** 30ºC ± 2°C / RH 75% ± 5% for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence andComparative Dissolution Profile	**Name:** ULTANE® Solution for inhalation **Manufacturer**: Maruishi Pharmaceutical Co. Ltd. Japan.
	Analytical method validation/verificationof product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type III Amber Glass Bottles, Poly-seal Closure.
	Stability study data of drug product, shelflife and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:Duration:** 36 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.

Evaluation by PEC:

Section	Observations
1.3.4	• Please submit legalized GMP certificate and Certificate of Pharmaceutical product. • Please submit valid drug distribution license of importer which should be in force till date.

During initial scrutiny, following observations / shortcomings were observed:

Decision: Deferred for submission of reply to the above cited shortcoming.

8.	**Import** **Molecules**

	Name, address of Applicant / Importer	**M/s Martin Dow Limited** **Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 595 Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: iv. Plot # 32, Sec:16 K.I.A Karachi. v. 1st floor, plot # 211, Sec: 23 K.I.A Karachi vi. Plot # 116, Sec: 15 K.I.A Karachi. Validity: 16-06-2024 Status: **VALID**
	Name and address of marketing authorization holder (abroad)	**M/s CHAI TAI TIANQING PHARMACEUTICAL GROUP CO. LTD.** No. 369 Yuzhou South Road Haizhou District, Lianyungang, Jiangsu Province 222062, **China.**
	Name, address of manufacturer(s)	**M/s CHAI TAI TIANQING PHARMACEUTICAL GROUP CO. LTD.** No. 369 Yuzhou South Road Haizhou District, Lianyungang, Jiangsu Province 222062, **China.**
	Name of exporting country	**China.**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 21st February 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 231100B0/008128) dated 13-02-2023 issued by Jiangsu Medical Products Administration. The CoPP specifies free sale status of the product in country of export along with its availability. The certifying authority arrange for periodic inspection which validity is 03 years. • **GMP Certificate # 20160312:** ✓ Issued on 12-11-2022 ✓ Validity: 03 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP for production of antitumor (oncological) tablet.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **Chia Tai Tianqing Pharmaceutical Group Co. Ltd.** No. 369 Yuzhou South Road Haizhou District, Lianyungang, Jiangsu Province, **China.** The letter certifies that the drug product manufacturer in China authorizes **M/s Martin Dow Limited** **Address:** Plot # 37, Sector 19, Korangi Industrial Area, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **Dasanib Tablet 20 mg** 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. No. 10289 Dated: 18th April 2023
	Details of fee submitted	PKR 150000/-: 16th February 2023 Slip # 9121620726
	The proposed proprietary name / brand name	**Dasanib Tablet 20 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dasatinib ..... 20 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Kinase Inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**SPRYCEL®** USFDA approved formulation.
	For generic drugs (me-too status)	**SPRYCEL®** (Reg. # 47554)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** M/s Lianyungang Runzhong Pharmaceutical. Co. Ltd. **Address:** No. 16, Jinqiao Road, Dapu Industrial Park, Lianyungang, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C / RH 75% ± 5% for 06 months. **Real time:** 30ºC ± 2°C / RH 75% ± 5% for 36 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of

		drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** SPRYCEL tablet 20mg **Manufacturer**: Bristol Myers Squibb Pharma EEIG.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PA/AL/PVC Cold formed foil & Aluminum foil
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40°C ±2°C **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 36 months **Temperature:** 30°C ±2°C **Relative Humidity:** 75% ± 5%.
Remarks of the Evaluator:		
Decision: Approved as per policy of inspection of manufacturer abroad.		
9.	**Import Molecules**	
	Name, address of Applicant / Importer	**M/s Martin Dow Limited** **Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 595 Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: vii. Plot # 32, Sec:16 K.I.A Karachi. iii. 1st floor, plot # 211, Sec: 23 K.I.A Karachi ix. Plot # 116, Sec: 15 K.I.A Karachi. Validity: 16-06-2024 Status: **VALID**
	Name and address of marketing authorization holder (abroad)	**M/s CHAI TAI TIANQING PHARMACEUTICAL GROUP CO. LTD.** No. 369 Yuzhou South Road Haizhou District, Lianyungang, Jiangsu Province 222062, **China.**
	Name, address of manufacturer(s)	**M/s CHAI TAI TIANQING PHARMACEUTICAL GROUP CO. LTD.** No. 369 Yuzhou South Road Haizhou District, Lianyungang, Jiangsu Province 222062, **China.**
	Name of exporting country	**China.**

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Original & Legalized</u>** **Date of Legalization:** 21st February 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 20230040) dated 18-01-2023 issued by Jiangsu Medical Products Administration. The CoPP specifies free sale status of the product in country of export along with its availability. The certifying authority arrange for periodic inspection which validity is 03 years. • **GMP Certificate # 20160312:** ✓ Issued on 12-11-2022 ✓ Validity: 03 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP for production of antitumor (oncological) tablet.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **Chia Tai Tianqing Pharmaceutical Group Co. Ltd.** No. 369 Yuzhou South Road Haizhou District, Lianyungang, Jiangsu Province, **China.** The letter certifies that the drug product manufacturer in China authorizes **M/s Martin Dow Limited** **Address:** Plot # 37, Sector 19, Korangi Industrial Area, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **Dasanib Tablet 50 mg** 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. No. 10288 Dated: 18th April 2023
	Details of fee submitted	PKR 150000/-: 16th February 2023 Slip # 712623059560
	The proposed proprietary name / brand name	**Dasanib Tablet 50 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dasatinib ..... 50 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Kinase Inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	28's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	**SPRYCEL®** USFDA approved formulation.
	For generic drugs (me-too status)	**SPRYCEL®** (Reg. # 47555)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Name:** M/s Lianyungang Runzhong Pharmaceutical. Co. Ltd. **Address:** No. 16, Jinqiao Road, Dapu Industrial Park, Lianyungang, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C / RH 75% ± 5% for 06 months. **Real time:** 30ºC ± 2°C / RH 75% ± 5% for 36 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** SPRYCEL tablet 50mg **Manufacturer**: Bristol Myers Squibb Pharma EEIG.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PA/AL/PVC Cold formed foil & Aluminum foil
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 36 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.
Remarks of the Evaluator:		

Decision: Approved as per policy of inspection of manufacturer abroad.		
10.	**Name, address of Applicant / Importer**	**M/s Martin Dow Limited** **Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 595 Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: vii. Plot # 32, Sec:16 K.I.A Karachi. viii. 1st floor, plot # 211, Sec: 23 K.I.A Karachi ix. Plot # 116, Sec: 15 K.I.A Karachi. Validity: 16-06-2024 Status: **VALID**
	Name and address of marketing authorization holder (abroad)	**DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL Sicil No: 70061 **Turkey.**
	Name, address of manufacturer(s)	**DEVA HOLDING A.S.** Cerkezkoy Organize Sanayi Bölgesi, Karaağaç Mah. Fatih bulvarı No:26, Kapaklı – TEKİRDAĞ **Turkey.**
	Name of exporting country	**Turkey**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Original & Legalized</u>** **Date of Legalization:** 06th April 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2023/1460) dated 06-04-2023 issued by Turkish Medicines and Medical Device Agency. The CoPP specifies free sale status of the product in country of export along with its availability. The certifying authority arrange for periodic inspection which validity is 03 years. • **GMP Certificate # TR/GMP/2022/292:** ✓ Issued on 10-11-2022 ✓ Validity: 03 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP for production of anticancer (oncological) lyophilized injectable vials.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL **Turkey.** The letter certifies that the drug product manufacturer in Turky authorizes **M/s Martin Dow Limited** **Address:** Plot # 37, Sector 19, Korangi Industrial Area, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **TARSINIB Tablet 100mg** in Pakistan. The letter was issued on 02.05.2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 15813 Dated: 22nd June 2023
	Details of fee submitted	PKR 150000/-: 09th May 2023 Slip # 40667696
	The proposed proprietary name / brand name	**Tarsinib Tablet 100 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Erlotinib HCl 109.28mg equivalent to Erlotinib..... 100 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent *(Protein kinase inhibitor)*
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Tarceva®** by Roche Pharma Germany MHRA approved (PLGB 00031/0905)
	For generic drugs (me-too status)	Erlocip by AJ Mirza (Reg. # 88383)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**M/S HETERO LABS LIMITED UNIT-I** SY. NO.10, I.D.A., GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C /RH ± 75°C for 06 months. **Real time:** 25 ± 2°C / RH 60°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	**Name:** Tarceva® 100mg Tablet **Manufacturer**: Roche Germany
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Blister of a two layer PVC film laminated with Aclar (Polychlorotrifluoroethylene, PCTFE) film on the inner side and a backing of aluminum foil with heat seal lacquer.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.
Evaluation by PEC:		
Decision: Approved as per policy of inspection of manufacturer abroad.		
11.	**Name, address of Applicant / Importer**	**M/s Martin Dow Limited** **Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 595 Address: Plot # 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: x. Plot # 32, Sec:16 K.I.A Karachi. xi. 1st floor, plot # 211, Sec: 23 K.I.A Karachi xii. Plot # 116, Sec: 15 K.I.A Karachi. Validity: 16-06-2024 Status: **VALID**
	Name and address of marketing authorization holder (abroad)	**DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL Sicil No: 70061 **Turkey.**
	Name, address of manufacturer(s)	**DEVA HOLDING A.S.** Cerkezkoy Organize Sanayi Bölgesi, Karaağaç Mah. Fatih bulvarı No:26, Kapaklı – TEKİRDAĞ **Turkey.**
	Name of exporting country	**Turkey**

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Original & Legalized</u>** **Date of Legalization:** 04th March 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2023/793) dated 27-02-2023 issued by Turkish Medicines and Medical Device Agency. The CoPP specifies free sale status of the product in country of export along with its availability. The certifying authority arrange for periodic inspection which validity is 03 years. • **GMP Certificate # TR/GMP/2022/292:** ✓ Issued on 10-11-2022 ✓ Validity: 03 years from date of issuance. ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP for production of anticancer (oncological) lyophilized injectable vials.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **DEVA HOLDING A.S.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece - İSTANBUL **Turkey.** The letter certifies that the drug product manufacturer in Turky authorizes **M/s Martin Dow Limited** **Address:** Plot # 37, Sector 19, Korangi Industrial Area, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **TARSINIB Tablet 100mg** in Pakistan. The letter was issued on 02.05.2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 15814 Dated: 22nd June 2023
	Details of fee submitted	PKR 150000/-: 09th May 2023 Slip # 492215003658
	The proposed proprietary name / brand name	**Tarsinib Tablet 150 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Erlotinib HCl 163.92 mg equivalent to Erlotinib..... 150 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent *(Protein kinase inhibitor)*
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	30's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	**Tarceva®** 150mg by Roche Pharma Germany MHRA approved (PLGB 00031/0905)
	For generic drugs (me-too status)	Erlotec by Revive Pharmakon (Reg # 90739)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**M/S HETERO LABS LIMITED UNIT-I** SY. NO.10, I.D.A., GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API **At accelerated** 40ºC ± 2°C /RH ± 75°C for 06 months. **Real time:** 25 ± 2°C / RH 60°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	**Name:** Tarceva® 100mg Tablet **Manufacturer**: Roche Germany
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Blister of a two layer PVC film laminated with Aclar (Polychlorotrifluoroethylene, PCTFE) film on the inner side and a backing of aluminum foil with heat seal lacquer.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40ºC ±2ºC **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 30ºC ±2ºC **Relative Humidity:** 75% ± 5%.

Evaluation by PEC:		
Decision: Approved as per policy of inspection of manufacturer abroad.		
12.	**Name, address of Applicant / Importer**	**M/s A.J. MIRZA PHARMA (PVT.) LTD** **Address 01: 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi.** **Address 02: Ground Floor, Plot # 44, Sector 27, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 235 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Address of Godown: Ground Floor, Plot # 44, Sector 27, Korangi Industrial Area, Karachi.Validity: 21-12-2027 Status: **VALID**
	Name and address of marketing authorization holder (abroad)	**M/s Cipla Ltd.** Plot # S-103 to S-105, S-107 to S-112, L-147/1 to L-147/3, L-147/A & l-138 Verna Industrial Estate, Verna,, Salcette, Goa, India.
	Name, address of manufacturer(s)	**M/s Cipla Ltd.** Plot # S-103 to S-105, S-107 to S-112, L-147/1 to L-147/3, L-147/A & l-138 Verna Industrial Estate, Verna,, Salcette, Goa, India.
	Name of exporting country	**India.**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original & Legalized** **Date of Legalization:** 19th January 2023 • **CoPP:** Firm has submitted original, legalized CoPP certificate (No. **789/MFG/WHO-GMP/DFDA/2022/2893**) dated 16-12-2022 issued by Directorate of Food & Drugs AdministrationDhanwantari, Opp. The Shrine of Holy Cross, Bambolim,Goa, India. (Free sale Certificate) • **GMP Certificate # 789/MFG/WHO-GMP/DFDA/2022/886:** ✓ Issued on 23-06-2022 ✓ Validity: 13-06-2025 ✓ Certificate confirms that drug manufacturer complies with the requirement of GMP for production of Soft Gelatin Capsules (cytotoxic).
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **CIPLA LTD.** Having office at **Cipla House Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbau, India.** The letter certifies that the drug product manufacturer in India authorizes **M/s A.J. MIRZA Pharma (Pvt.) Ltd.** **Address:** 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. As a sole marketing authorization holder in Pakistan to apply for registration of **Enzalutamide Capsule 40mg** in Pakistan. The letter was issued on 02.05.2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 15814 Dated: 22nd June 2023
	Details of fee submitted	PKR 150000/-: 09th May 2023 Slip # 492215003658
	The proposed proprietary name / brand name	**Xylutide Capsule 40 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Enzalutamide..... 40 mg
	Pharmaceutical form of applied drug	Soft Gelatin Capsule
	Pharmacotherapeutic Group of (API)	Androgen Receptor Inhibitor
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	28's & 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**XTANDI®** 40mg capsules USFDA approved formulation
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**M/s Cipla Limited-Bommasandra** Plot # 285, 286 and 287. Bommasandra-Jigani Link Road, Industrial Area, KIADB 4th Phase Bengaluru – 560105, Karnataka, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of batches of API **At accelerated** 40ºC ± 2°C /RH ± 75°C for 06 months. **Real time:** 30 ± 2°C / RH 6°C for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development,

		manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Name:** XTANDI Capsule 40 mg **Manufacturer**: Astellas Pharma USA.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Blister of a two layer PVC film laminated with Aclar (Polychlorotrifluoroethylene, PCTFE) film on the inner side and a backing of aluminum foil with heat seal lacquer.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches **Accelerated Storage Conditions:** **Duration:** 06 months **Temperature:** 40°C ±2°C **Relative Humidity:** 75% ± 5%. **Long term Storage Conditions:** **Duration:** 24 months **Temperature:** 30°C ±2°C **Relative Humidity:** 65% ± 5%.
Evaluation by PEC:		
Decision: Approved as per policy of inspection of manufacturer abroad.		

Agenda of Evaluator PEC-IX

Case 1: The board in its 257th meeting decided that drugs for treatment of cancer, viral diseases, thalassemia, immunosuppressant, vaccine and sera, new molecules / formulations, blood factors and bags will be given priority consideration.

13.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Ms. Beenish Ashfaq CNIC 37406-4643954-6
	Name and address of marketing authorization holder (abroad)	M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name, address of manufacturer(s)	**M/s NAPROD LIFE SCIENCES Pvt. Ltd.** Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:**

		Firm has submitted original, legalized CoPP (No. COPP/CERT/KD/119213/2022/11/42075/205614) dated 09.09.2022 valid till 27.04.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India** . Name and dosage form on the CoPP certificate mentioned is "Docetaxel injection USP (1ml, 4ml, 6ml, 8ml) strength 20mg" and name of the product license holder is M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/KD/111021/2022/11/40081 dated 28.04.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/ NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India**.** having its manufacturing site at same address. Certificate valid till 27.04.2025. As per certificate, last inspection of the manufacturer was conducted on 24.02.2022 & 25.02.2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted Letter of Authorization. The letter specifies that product license holder i.e. M/s NAPROD LIFE SCIENCES Pvt. Ltd has a facilitator M/s Miles International Mumbai India, the facilitator M/s Miles International appoints M/s Lab Diagnostic System (SMC) Pvt. Ltd. to apply for registration of their product Docetaxel Injection USP 20mg/ml with Drug Regulatory Authority on their behalf. The agreement will be valid till 31st March 2027. The agreement is not notarized.
	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. 13766 dated 02.06.2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 442090369 Dated: 30.09.2022

	The proposed proprietary name / brand name	**DOCESOLE 20mg/ml Concentrate for Infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml vial contains: Docetaxel……20mg.
	Pharmaceutical form of applied drug	Clear colourless to pale yellow solution, concentrate for IV infusion.
	Pharmacotherapeutic Group of (API)	Taxanes ATC Code: L01CD02
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	DOCETAXEL 20MG/ML KABI MHRA Approved.
	For generic drugs (me-too status)	Mebrexel 20mg Inj Reg. No. 045608 M/s CCL Pharma Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co. Ltd. No. 508, Maodian Road, Qingpu District Shanghai, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (DXT201904027, DXT201906036, DXT201906037, DXT201907038) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 6 months (Real time) Batch No. DCA201411002, DCA201411003, DCA201411004
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (NN0058,NN0059, NN0060.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e.

		Docetaxel Injection 20mg/ml Batch No. 6F286A manufactured by Sanofi exp_date:_, by performing following tests; pH, Assay, Particulate matter.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Type-I glass vials with rubber stopper, aluminium and plastic flip-off seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30°C ± 2°C, 75% ± 5% for 12 months**. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. NN0058, NN0059, NN0060. NN1195-A,
	Therapeutic indications in USFDA.	Docetaxel Injection is a microtubule inhibitor indicated for: • **Breast Cancer (BC):** single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1) • **Non-Small Cell Lung Cancer (NSCLC):** single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2) • **Hormone Refractory Prostate Cancer (HRPC):** with prednisone in androgen independent (hormone refractory) metastatic prostate cancer (1.3) • **Gastric Adenocarcinoma (GC):** with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4) • **Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN):** with cisplatin and fluorouracil for induction treatment of locally

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	3.2.P.2	In pharmaceutical equivalence only pH, Assay & Particulate matter tests are done for comparison. Why all pharmacopoeial tests are not performed for establishing pharmaceutical equivalence. The Reference product specifications mentioned are IP, why comparison is not done with a product having USP specifications as your product are as per USP specifications. Further address of manufacturer and expiry date of reference product are also required.
3.	3.2.P.8	Stability studies data for full shelf life claimed is required.
4.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.

Decision: Deferred for submission of reply to above cited shortcomings.

14.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024

		Status: License to sell drugs as distributor. **Technical Person:** Ms. Beenish Ashfaq CNIC 37406-4643954-6
	Name and address of marketing authorization holder (abroad)	M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name, address of manufacturer(s)	**M/s NAPROD LIFE SCIENCES Pvt. Ltd.** Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (No. COPP/CERT/KD/119213/2022/11/42075/205614) dated 09.09.2022 valid till 27.04.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "Docetaxel injection USP (1ml, 4ml, 6ml, 8ml) strength 20mg/ml" and name of the product license holder is M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/KD/111021/2022/11/40081 dated 28.04.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/ NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India**.** having its manufacturing site at same address. Certificate valid till 27.04.2025. As per certificate, last inspection of the manufacturer was conducted on 24.02.2022 & 25.02.2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted Letter of Authorization. The letter specifies that product license holder i.e. M/s NAPROD LIFE SCIENCES Pvt. Ltd has a facilitator M/s Miles International Mumbai India, the facilitator M/s Miles International appoints M/s Lab Diagnostic System (SMC) Pvt. Ltd. to apply for registration of their product Docetaxel Injection USP 80mg/4ml with Drug Regulatory Authority on their behalf. The agreement will be valid till 31st March 2027. The agreement is not notarized.
	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. 13162 dated 29.05.2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 457189188 Dated: 30.09.2022
	The proposed proprietary name / brand name	**DOCESOLE 80mg/4ml concentrate for infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml vial contains: Docetaxel……80mg.
	Pharmaceutical form of applied drug	Clear colourless to pale yellow solution, concentrate for IV infusion.
	Pharmacotherapeutic Group of (API)	Taxanes ATC Code: L01CD02
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	DOCETAXEL 80MG/4ML KABI MHRA Approved.
	For generic drugs (me-too status)	Mebrexel 80mg Inj Reg. No. 045606 M/s CCL Pharma Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co. Ltd. No. 508, Maodian Road, Qingpu District Shanghai, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (DXT201904027, DXT201906036, DXT201906037, DXT201907038) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 6 months (Real time)

		Batch No. DCA201411002, DCA201411003, DCA201411004
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (NN0062,NN0063, NN0061.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Docetaxel Injection 20mg/ml Batch No. 6F286A manufactured by Sanofi exp_date:_, by performing following tests; pH, Assay, Particulate matter.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Type-I glass vials with rubber stopper, aluminium and plastic flip-off seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30°C ± 2°C, 75% ± 5% for 12 months**. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. NN0061, NN0062, NN0063. NN2152-B,
	Therapeutic indications in USFDA.	Docetaxel Injection is a microtubule inhibitor indicated for: • **Breast Cancer (BC):** single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1) • **Non-Small Cell Lung Cancer (NSCLC):** single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2) • **Hormone Refractory Prostate Cancer (HRPC):** with prednisone in androgen independent (hormone refractory) metastatic prostate cancer (1.3) • **Gastric Adenocarcinoma (GC):** with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4) • **Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN):** with cisplatin and fluorouracil for induction treatment of locally

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	3.2.P.2	Pharmaceutical equivalence of product having strength 20mg/ml is submitted. Same is submitted in dossier of product having strength of 20mg/1ml. Proper pharmaceutical equivalence studies are required.
3.	3.2.P.3.5	Process validation of strength 120mg/6ml is submitted. Validation studies of 80mg/4ml strength are required.
4.	3.2.P.8	Stability studies data for full shelf life claimed is required.

5.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.	
Decision: Deferred for submission of reply to above cited shortcomings.			
15.	**Name, address of Applicant / Importer**		M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer		**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Ms. Beenish Ashfaq CNIC 37406-4643954-6
	Name and address of marketing authorization holder (abroad)		M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name, address of manufacturer(s)		**M/s NAPROD LIFE SCIENCES Pvt. Ltd.** Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India.
	Name of exporting country		India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)		**CoPP:** Firm has submitted original, legalized CoPP (No. COPP/CERT/KD/119213/2022/11/42075/205614) dated 09.09.2022 valid till 27.04.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "Docetaxel injection USP (1ml, 4ml, 6ml, 8ml) strength 20mg/ml" and name of the product license holder is M/s NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/KD/111021/2022/11/40081 dated 28.04.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/ NAPROD LIFE SCIENCES Pvt. Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisal, Dist. Palghar 401506 Maharashtra State India**.** having its manufacturing site at same address. Certificate valid till 27.04.2025. As per certificate, last inspection of the manufacturer was conducted on 24.02.2022 & 25.02.2022.
	Details of letter of authorization / sole agency agreement		Firm has submitted Letter of Authorization. The letter specifies that product license holder i.e. M/s NAPROD LIFE SCIENCES Pvt. Ltd has a facilitator M/s Miles International Mumbai India, the facilitator M/s Miles International appoints M/s Lab Diagnostic System

		(SMC) Pvt. Ltd. to apply for registration of their product Docetaxel Injection USP 80mg/4ml with Drug Regulatory Authority on their behalf. The agreement will be valid till 31st March 2027. The agreement is not notarized.
	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. 13161 dated 29.05.2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 6438456057 Dated: 30.09.2022
	The proposed proprietary name / brand name	**DOCESOLE 120mg/6ml concentrate for infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 6ml vial contains: Docetaxel……120mg.
	Pharmaceutical form of applied drug	Clear colourless to pale yellow solution, concentrate for IV infusion.
	Pharmacotherapeutic Group of (API)	Taxanes ATC Code: L01CD02
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	DOCETAXEL 120MG/6ML KABI MHRA Approved.
	For generic drugs (me-too status)	Doxetal 120mg/6ml Inj Reg. No. 092154 M/s Rotex Pharma
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Jinhe Bio-Pharmaceutical Co. Ltd. No. 508, Maodian Road, Qingpu District Shanghai, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (DXT201904027, DXT201906036, DXT201906037, DXT201907038) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 65%±5% RH: 24 months (Real time) Batch No. DCA201411002, DCA201411003, DCA201411004
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (NN0064,NN0065, NN0066.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Docetaxel Injection 20mg/ml Batch No. 6F286A manufactured by Sanofi exp_date:_, by performing following tests; pH, Assay, Particulate matter.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Type-I glass vials with rubber stopper, aluminium and plastic flip-off seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. **The real time stability study data is conducted at 30℃ ± 2℃, 75% ± 5% for 12 months**. Accelerated at 40±2℃/75±5%RH for 6 months. Batch No. NN0064, NN0065, NN0066.
	Therapeutic indications in USFDA.	Docetaxel Injection is a microtubule inhibitor indicated for: • **Breast Cancer (BC):** single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1) • **Non-Small Cell Lung Cancer (NSCLC):** single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2) • **Hormone Refractory Prostate Cancer (HRPC):** with prednisone in androgen independent (hormone refractory) metastatic prostate cancer (1.3) • **Gastric Adenocarcinoma (GC):** with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4)

		• **Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN):** with cisplatin and fluorouracil for induction treatment of locally

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	3.2.P.2	Pharmaceutical equivalence of product having strength 20mg/ml is submitted. Same is submitted in dossier of product having strength of 20mg/1ml. Proper pharmaceutical equivalence studies are required.
3.	3.2.P.8	Stability studies data for full shelf life claimed is required.
4.	3.2.P.8	Supporting data [Chromatograms(assay run, system suitability, standard run, impurities etc), HPLC log, evidence of CFR-21 compliance, spectra etc] of testing of Trial batches is required.

Decision: Deferred for submission of reply to above cited shortcomings.

Case 2: The Authority in its 165th meeting held on 20th July 2023, approved out-of-queue consideration of Form 5-Fapplications of following molecules received till 31st December, 2023, keeping in view of their repeated shortage/ non-availability reports in the market and to ensure timely access of these drugs to public:

1. Labetalol Injection
2. Calcium gluconate Injection
3. Digoxin Injection
4. Propofol Injection
5. Cholestyramine powder/ Sachet
6. Lithium Carbonate Tablet
7. Pilocarpine Eye Drops
8. Heparin Injection
9. Divalproex sodium Tablet and Injection
10. Anti-D injection
11. Streptokinase Injection
12. Octreotide acetate Injection
13. Carbamazepine Tablet
14. Penicillin-G Benzathine Injection
15. Fucidic acid cream
16. Calcitonin Injection
17. Potassium chloride Tablet
18. **Contrast media**
19. Protamine Sulphate Injection

16.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.
	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Mr. Ahmad Aman CNIC 3740611481985
	Name and address of marketing authorization holder (abroad)	M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra. India
	Name, address of manufacturer(s)	**M/s Unijules Life Sciences Limited,** D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. MS. India

	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. COPP/CERT/ND/132390/2023/11/47980/231380) dated 17.11.2023 valid till 28.09.2025 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "VISOATE I, Diatrizoate Meglumine and Diatrizoate sodium Injection USP 20 ml pack. " and name of the product license holder is M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/ND/119226/2022/11/42260 dated 29.09.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra India having its manufacturing site at same address. Certificate valid till 28.09.2025 As per certificate, last inspection of the manufacturer was conducted on 2nd and 3rd September, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted a distribution certificate. The certificate specifies that product license holder i.e. M/s Unijules Life Sciences Ltd has certified M/s Lab Diagnostic System (SMC) Pvt. Ltd as their preferred distributor for the territory of Pakistan. The agreement will be valid till October 2024 The agreement is not notarized.
	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
	Eapp Tracking ID:	**Z7N-3R4-LBPS**
	Details of fee submitted	PKR 150,000/- vide slip No. 27441819713 Dated: 25.10.2023

	The proposed proprietary name / brand name	**VISOATE I 20ml Vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Diatrizoate Meglumine USP…..... 660 mg Diatrizoate Sodium USP..... 100 mg Equivalent to Iodine 370 mg/ml
	Pharmaceutical form of applied drug	Radioopaque contrast agent, supplied as sterile, aqueous solution, intended for intravascular administration.
	Pharmacotherapeutic Group of (API)	Watersoluble, nephrotropic, high osmolar X-ray contrast media ATC Code: V08AA01
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	1's. 20ml
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Could not be verified Discontinued in USFDA
	For generic drugs (me-too status)	Megluphin Inj Reg. No. 108475 M/s Bajwa Pharma Sheikhupura.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, 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	**Diatrizoic acid:** M/s Justesa Imagen S. A, Avda, San Pablo, 27 E 28823 Coslada, Madrid Spain. **Meglumine:** M/s Eagle Chemical Works Plot No. 29/A, 1st Phase, GIDC VAPI 396 195 Dist. Valsad Gujrat State India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (5569) (MGM-001/17, MGM-002/17, MGM-003/17) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 60%±5% RH: 48 months (Real time) Batch No. 3.883, 3.884, 3.885 Batch No. 4326, 4327, 4328 Maglumine: MGM-001/14, MGM-002/14, MGM-003/14, Long term for 36 months, at 30℃± 2℃, 65% ±5% RH.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (0223H2301, 0223H2302.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Trazograf 76% Batch No. I0Z23031. EXP 06.2026 mfg 07,2023 manufactured by **Unique Pharmaceutical labs**, by performing following tests; Physical appearance, identification, particulate matter, extractable volume, pH, sterility, BET, free aromatic amine, Iodine and iodide content, Assay. Pictorial evidence is submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Diatrizoate meglumine and diatrizoate sodium injection USP in colorless 20 ml USP type I vial with 20 mm bromobutyl rubber stopper and 20 mm aluminium flip off hook seal of navy blue color labeled in unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. The real time stability study data is conducted at 30°C ± 2°C, 75% ± 5% for 36 months. Accelerated at 40±2°C/75±5%RH for 6 months. Batch No. 0223C1801, 0223C1901, 0223B2001,
	Therapeutic indications in USFDA.	Diatrizoate Meglumine and Diatrizoate Sodium Solution is indicated for radiographic examination of segments of the gastrointestinal tract (esophagus, stomach, proximal small intestine, and colon). The preparation is particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous. Diatrizoate Meglumine and Diatrizoate Sodium Solution may also be used as an adjunct to contrast enhancement is computed tomography of the torso (body imaging); the preparation is indicated, in conjunction with intravenous administration of a radiopaque contrast agent, when unenhanced imaging may not provide sufficient definition in distinguishing normal loops of bowel from adjacent organs or areas of suspected pathology

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	-	COPP is required to be legalized.
3.	-	RRA reference provided is discontinued. Valid RRA reference is require.
4.	3.2.P.8	The batches whose stability data is submitted, their executed BMRs are also required.

Decision: Deferred for submission of reply to above cited shortcomings.

17.	**Name, address of Applicant / Importer**	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi.

	Details of Drug Sale License of importer	**License No**: 01-374-0006-96845D **Address**: Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi. Address of Godown: NA **Validity**: 04.08.2024 **Status**: License to sell drugs as distributor. **Technical Person:** Mr. Ahmad Aman CNIC 3740611481985
	Name and address of marketing authorization holder (abroad)	M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra. India
	Name, address of manufacturer(s)	**M/s Unijules Life Sciences Limited,** D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. MS. India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. COPP/CERT/ND/132212/2023/11/48048/231393) dated 24.11.2023 valid till 17.10.2024 issued by Joint commissioner (HQ) & Controlling Authority Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state **India.** Name and dosage form on the CoPP certificate mentioned is "VISOATE I, Diatrizoate Meglumine and Diatrizoate sodium Injection USP 20 ml pack. " and name of the product license holder is M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra **India.** The certificate also confirms that the applied formulation is actually on the market in the exporting country. Pakistan is mentioned as importing country on COPP **GMP:** Applicant has submitted copy of GMP certificate No. NEW-WHO-GMP/CER/ND/119226/2022/11/42260 dated 29.09.2022 issued by **Food & Drug Administration M.S Bandra (E) Mumbai, Maharashtra state India** in the name of M/s Unijules Life Sciences Ltd. . D-82, M.I.D.C area Cross Road No. 4-A, Hingna, District Nagpur. Maharashtra India having its manufacturing site at same address. Certificate valid till 28.09.2025 As per certificate, last inspection of the manufacturer was conducted on 2nd and 3rd September, 2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted a distribution certificate. The certificate specifies that product license holder i.e. M/s Unijules Life Sciences Ltd has certified M/s Lab Diagnostic System (SMC) Pvt. Ltd as their preferred distributor for the territory of Pakistan. The agreement will be valid till October 2024 The agreement is not notarized.
	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
	Eapp Tracking ID:	**G43-7VZ-ZM4N**
	Details of fee submitted	PKR 150,000/- vide slip No. 1996863096 Dated: 2023-10-25
	The proposed proprietary name / brand name	**VISOATE G 370mgI/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Diatrizoic acid…..... 632.3 mg Meglumine…..... 159.4 mg Equivalent to Iodine 370 mg/ml
	Pharmaceutical form of applied drug	Radioopaque contrast agent, supplied in 100mL pet bottle for oral administration.
	Pharmacotherapeutic Group of (API)	Watersoluble, nephrotropic, high osmolar X-ray contrast media ATC Code: V08AA01
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	100ml
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	GASTROGRAFIN DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM 66%;10% USFDA Approved.
	For generic drugs (me-too status)	Gastrografin Solution Reg. No. 000700 M/s Bayer Pak (Pvt.) ltd. Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, 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	**Diatrizoic acid:** M/s Justesa Imagen S. A, Avda, San Pablo, 27 E 28823 Coslada, Madrid Spain. **Meglumine:** M/s Eagle Chemical Works Plot No. 29/A, 1st Phase, GIDC VAPI 396 195 Dist. Valsad Gujrat State India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (5569) (MGM-001/17, MGM-002/17, MGM-003/17)

		and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The stability conditions with time durations are; 40±2 ℃ 75%±5 RH: 6 months (Accelerated) 25 ºC±2℃ 60%±5% RH: 48 months (Real time) Batch No. 3.883, 3.884, 3.885 Batch No. 4326, 4327, 4328 Maglumine: MGM-001/14, MGM-002/14, MGM-003/14, Long term for 36 months, at 30℃± 2℃, 65% ±5% RH.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (0067D2001, 0067B2001, 0067A2001)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Gastrografin Batch No. . EXP____mfg manufactured by **Bracco Diagnostic Inc NJ**, by performing following tests; Physical appearance, Minimum fill, pH, identification, Weight per mL, Iodine and Iodide, Microbial test, Assay. Pictorial evidence is not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	100 ml amber colour pet bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. The real time stability study data is conducted at 30℃ ± 2℃, 65% ± 5% for 36 months. Accelerated at 40±2℃/75±5%RH for 6 months. Batch No. 0067A1601, 0067A1701, 0067A1801.
	Therapeutic indications in USFDA.	Diatrizoate Meglumine and Diatrizoate Sodium Solution is indicated for radiographic examination of segments of the gastrointestinal tract (esophagus, stomach, proximal small intestine, and colon). The preparation is particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous. Diatrizoate Meglumine and Diatrizoate Sodium Solution may also be used as an adjunct to contrast enhancement is computed tomography of the torso (body imaging); the preparation is indicated, in conjunction with intravenous administration of a radiopaque contrast agent, when unenhanced imaging may not provide sufficient definition in distinguishing normal loops of

		bowel from adjacent organs or areas of suspected pathology

Evaluation by PEC:

Sr. No.	Section	Observation
1.	-	Notarized Letter of Authorization is required.
2.	-	COPP is required to be legalized.
3.	1.5.9	The label applied does not indicate sodium salt. The innovator product uses both sodium salt and meglumine. Label needs to be revised as per innovator product along with submission of fee for pre-registration variation.
4.	3.2.P.2	Batch No. expiry date and mfg date of reference product (Gastrografin) is required. The picture submitted is generic picture of the product, pictorial evidence of actual pack used in pharmaceutical equivalence is required.
5.	3.2.P.8	The batches whose stability data is submitted, their executed BMRs are also required.

Decision: Deferred for submission of reply to above cited shortcomings.

Agenda of Evaluator PEC- XXIII

18.	**Name, address of Applicant / Importer**	M/s. Revive Health Care, Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan.
	Details of Drug Sale License of importer	License No: **05-352-0065-031159D** Address: Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan. Address of Go down: NA Validity: **21.05.2027** Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh
	Name, address of manufacturer(s)	M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# DA/6-134/09/10160 issued on 21-05-2023 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, and Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DGDA/6-134/09/195) issued by Directorate General of Drug Administration, Dhaka, Bangladesh and valid upto 30-09-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from M/s. Jenphar Bangladesh Limited. The letter specifies that the manufacturer appoints M/s Revive Health Care. 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.24504 , Date: 06-10-2023
	Details of fee submitted	PKR 75,000/- 19/09/2023
	The proposed proprietary name / brand name	Tasso Tablet 80mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Osimertinib (as mesylate)…..80mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors (L01EB04)
	Reference to Finished product specifications	In house
	Proposed Pack size	As per SRO
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Tagrisso 80mg Tablet (USFDA Approved)
	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	ShengDa Pharmaceutical Co., Limited.
	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 3 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 3 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 Tagrisso 80mg Tablet (M/s. AstraZeneca) 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	HDPE bottle
	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 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:

Therapeutic indications TAGRISSO as monotherapy is indicated for:

- the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.
- the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations.
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit product specific letter of authorization from the Product License Holder, since the submitted authorization letter was not specified the product.
2.	1.3.5	The applied product is in L01 group i.e. cytotoxic drug and as per decision of Registration Board in its 282nd meeting, "*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self-contained facilities and manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drug*" Accordingly evidence of self-contained or dedicated facility of manufacturer abroad shall be submitted.
3.	3.2.S.2.1	Provide the complete manufacturing address of drug substance manufacturer, since you have only specified the title of drug substance manufacturer.
4.	3.2.S.4.1-3.2.S.4.2	Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.
5.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.
6.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.
7.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the product.
8.	3.2.S.7	Submit stability data of drug substance performed both at accelerated and long term conditions till the claimed re-test period, since you have only submitted the data of 2 time points i.e. 1st and 3rd month.
9.	3.2.P.2.6	Innovator product claimed that tablets are formulated to be dispersible, when dosing of whole tablets is not possible, tablets may be administered as an aqueous dispersion. Reference to the innovator claim, did the applied formulation also dispersed in the similar manner as of innovator product. Further, did you performed the study for Use of Tablet Dispersion and impact of dispersion preparation on physiochemical properties of the final dosage form were assessed while formulation development.
10.	Conclusion of CDP report stated that test/applied formulation is the product of M/s. Beacon Pharmaceuticals, (Faridpur,sreepur,gazipur) Bangladesh, validation protocol claims that the Tasso tablet i.e. the applied product is of M/s. Julphar Bangladesh Ltd.(Gazipur,Sreepur) while the product license holder is M/s. Jenphar Bangladesh Ltd. (Vill-Faridpur, PS-Sreepur Dis-Gazipur).Clarification is required regarding the disparity observed related to the manufacturer of drug product in different section of CTD dossier, further, submitted the complete address of drug product manufacturer, since all three mentioned manufacturer have same address.	
11.	3.2.P.5.1	Justify the dissolution acceptance limit i.e. NLT 80% (Q) within 45 minutes adopted for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes.

12.	3.2.P.5.4	Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.	
13.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) of all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.	
Decision: Deferred for submission of reply to above cited shortcomings.			

Agenda of Evaluator PEC- IV

19.	Name, address of Applicant / Importer	**M/s Himmel Pharmaceuticals Pvt Ltd.** **Ground Floor, 6-Judicial Colony, Phase 1 (Ext) Shahrah Nazaria e Pakistan, Lahore., Pakistan**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174DD **Address:** Ground Floor, 6-Judicial Colony, Phase 1 (Ext) Shahrah Nazaria e Pakistan, Lahore., Lahore, Pakistan **Address of Godown:** NA **Validity:** 06/02/2024 **Status:** License to sell drugs as distributor **Renewal:** n/a
	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, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# DA/6-110/2016/13054) issued on 03-08-2022 by , Govt. of the people's republic of Bangladesh, **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP and Periodicity of inspections is mentioned Every two years
	Details of letter of authorization / sole agency agreement	Firm has submitted original, legalized sole agency agreement (letter of authorization) as product registration holder. The letter specifies that the manufacturer M/s BEACON Pharmaceuticals Limited. (9/B/2, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh) appoints M/s Himmel Pharmaceuticals Pvt Ltd, to register their products in Pakistan. The authorization letter is issued on 14-08-2022
	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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Dy. No. 7090 dated: 10-03-2023
	Details of fee submitted	PKR 75,000/- deposit Slip # 40940576306 PKR 75,000/- deposit Slip # 02183874171
	The proposed proprietary name / brand name	**Palbonix 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Palbociclib…….100mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	1 × 21's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	IBRANCE (Capsule) of USFDA approved
	For generic drugs (me-too status)	IBRANCE 100mg Capsule of M/s Pfizer Reg# 103787
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance..
	Name, address of drug substance manufacturer	Shandong Boyuan Pharmaceuticals Co., Ltd Address: Qiangjin Street, Jibei Economic Development Zone Jiyang County, Jinan City, Shandong China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months Batches: (180801GS, 180802GS, 180803GS)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Ibrance 100mg manufactured by Pfizer. UK by performing quality tests (Appearance, Assay, Microbial limit test. Impurities). The firm has submitted CDP with of Ibrance 100mg manufactured by Pfizer. UK in water, Acid media (pH 1.2),

		Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle
	Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 30˚C ± 2˚C / 65% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches Batches: 3430001, 3430002, 3430003,

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.3.5	Submitted GMP certificate of manufacturer does not specify that capsule section for anticancer is dedicated or otherwise.	Same GMP certificate submitted in which Dosage form Hard gelatin Capsule, controlled/Sustained Capsule in which all the categories are mentioned. Antiulcerants, Analgesics & Antipyretics, Antifungal, Vitamins & Minerals , Antivirals, Antiretroviral, Drug used in Anemia & other blood disorder, Antihypertensive & Cardiprotective, Antiplasmodics,Anti-infective, Anti-infective, Antiemetics, Anticonvulsants, Antiseizure, Immunosuppressant & Antirheumatic, Anticancer, Mucolytics & Expotorant, Dietry Supplements, Chelating Agent.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Summary reports for validation are submitted however no method and protocols are submitted.
3.	3.2.P.5.1	Innovator product dissolution limits are Q=80% in 30 minutes while your dissolution limits are NLT 75% in 45 minutes. Clarification is required regarding.	Firm refer their dissolution method to dissolution database of USFDA in which 45 minutes time pint is mentioned.
4.	3.2.P.5.2	Submit complete method for assay in analytical testing method of drug product.	complete method for assay in analytical testing method of drug product is submitted.

Decision: Approved as per policy of inspection of manufacturer abroad.
Registration letter will be issued upon submission of GMP certificate of drug product manufacturer wherein availability of dedicated Capsule (Anti-cancer/Oncology) section could be confirmed.

Agenda of Evaluator PEC-XX

20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt) Ltd, 16km Multan Road, Lahore**.
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt) Ltd, 16km Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	GMP Inspection report provided dated 04-02-2020 wherein firm was operating at satisfactory level of cGMP compliance
	Evidence of approval of manufacturing facility	Evidence for anti-cancer section regularization by DRAP to be provided (since lay out of anti-cancer section was upgraded)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26289 dated 31-10-2023
	Details of fee submitted	PKR 30,000/- Dated 27/09/2023
	The proposed proprietary name / brand name	**Ceload Tablet 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Capecitabine 500mg
	Pharmacotherapeutic Group of (API)	Antineoplastic/Antimetabolite
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	10's, 20's, 30's,
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xeloda tablet by Roche pharma USFDA approved
	For generic drugs (me-too status)	Xeloda tablet by Roche pharma Reg No 027375
	Name and address of API manufacturer.	M/s Shandong Lixin Pharmaceutical Co Ltd No. 9 Jinyang Road, Gaoqing Country Economic Development Zone, Zibo Shandong Province
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized informationrelated to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. C03-202211001 C03-202211002 C03-202211003 The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6months Accelerated stability data has not been provided
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against **Xeloda 500mg tablet** by **Excella GmbH & Co (Batch No B5452B02, Exp date 07-2024).** Quality parameters such as dissolution, Disintegration and assay against Test product. Firm has submitted CDP results of **Xeloda 500mg tablet** by **Excella GmbH & Co (Batch No B5452B02, Exp date 07-2024).** against Ceload 500mg tablet **(Batch No CAP-500/SB009)** in Acid media (pH 1.0-1.2) acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method verification of product	Firm has submitted analytical method verification study reports for drug substance as well as product.

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong Lixin Pharmaceutical Co Ltd No. 9 Jinyang Road, Gaoqing Country Economic Development Zone, Zibo Shandong Province		
API Lot No..Batch number	CO3-20220815		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	CAP-500-SB007	CAP-500-SB008	CAP-500-SB009
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	12/22	12/22	12/22
Date of Initiation	22/12/22	22/12/22	22/12/22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided copy of DML (No Lu2019420) issued by Shandong Food and Drug Administration valid till December 10,2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance certificate from DRAP is provided dated 27 .09.2022 wherein 2.8kg Capecitabine (Ph. Eur) Batch No CO3-20220815 is mentioned.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations
1.	Provide updated GMP status of finished product manufacturer
2.	Evidence for anti-cancer section regularization by DRAP to be provided (since lay out of anti-cancer section was upgraded)
3.	**2.3.R.1.1** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	**3.2.S.7** Provide stability data of Drug Substance (both Accelerated and Real time). Real time data to be provided up to shelf life, since already provided data is for period of 6 months only. Accelerated stability data as per zone IV-A condition has not been submitted

Decision: Deferred for submission of reply to above cited shortcomings.

Agenda of Evaluator PEC-XXI

Priority Applications of Human Drugs for Treatment of Cancer, as decided in 257th Registration Board Meeting.

21.	**Name, address of Applicant / Importer**	**M/s REVIVE HEALTH CARE** **Address:** 503, 5th Floor, Eden Heights, 6 Main Gulberg, Jail Road, District Lahore.
	Details of Drug Sale License of importer	**License No:** 05-352-0065-031159D **Address:** 503, 5th Floor, Eden Heights, 6 Main Gulberg, Jail Road, District Lahore. **Address of Godown:** N/A **Validity:** 21.05.2027 **Status:** VALID **Renewal:** 09 May, 2022.
	Name and address of marketing authorization holder (abroad)	**M/s SPAL Private Limited,** Plot No. 12, Biotech Park, Phase-II, Lalgadi Malakpet Shameerpet, Medchal-Malkajgiri Dist, Hyderabad, Telangan State – 500101, India.
	Name, address of manufacturer(s)	**M/s SPAL Private Limited,**

		Plot No. 12, Biotech Park, Phase-II, Lalgadi Malakpet Shameerpet, Medchal-Malkajgiri Dist, Hyderabad, Telangan State – 500101, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted **Scanned Copy** of legalized & notarized CoPP Certificate No. 4429584/TS/2023 dated 08-08-2023 issued by Drugs Control Administration, Telangana State for Carboplatin Concentrate for Solution for Infusion BP 450mg/45ml (CARBO SPAL-L 450), valid up to 05/10/2025. The CoPP mentions free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once in a year.
	Details of letter of authorization / sole agency agreement	Firm has submitted **Photocopy** of notarized 'Authorization Letter' issued by **M/s SP Accure Labs Private Limited**. The letter certifies that M/s SP Accure Labs Private Limited authorizes Revive Healthcare as their "EXCLUSIVE DISTRIBUTOR" for their products mentioned in **Annex 1**, for Pakistan. The authorization letter is signed dated 07/06/2022 and is valid till further Notice.
	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. 26291 dated 31 OCT 2023
	Details of fee submitted	PKR 150,000/- dated 26/10/2023 (Challan / Receipt # 0299928286)
	The proposed proprietary name / brand name	**CARBO SPAL-L 450 Concentrate for Solution for Infusion, 450mg/45ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Carboplatin (Ph.Eur.) … 10mg (BP Specifications)
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion
	Pharmacotherapeutic Group of (API)	L01XA02 Antineoplastic and Immunomodulating Agents, Platinum compounds.

	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	45ml Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	KEMOCARB 450mg INJECTION by M/s ATCO Laboratories Ltd.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	SUN Pharmaceutical Industries Limited, India. A-7/A-8, M.I.D.C, Industrial Area Ahmedabad Nagar 414111 Maharashtra State, India.
	Module-III Drug Substance:	Firm has submitted drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at Accelerated (40 ± 2°C / 75% RH ± 5%) for 6 Months and Real Time (25 ± 2°C / 60% RH ± 5%) for 72 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence / Comparative Analysis of their applied product against Reference product Carboplatin concentrate for Solution for Infusion, 450mg/45ml (B. No. 21NC0022, Mg. By Accord Healthcare Limited).
	Analytical method validation / verification of product	Firm has submitted Analytical Method Validation Reports for their applied product.
	Container closure system of the drug product	50ml amber coloured USP Type I glass vials with having 20mm serum laminated chlorobutyl rubber stopper and sealed with 20mm Light Blue coloured flip-off seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40° C ± 2° C 75% ± 5% RH for 6 months. The real time stability

		study data is conducted at 30° C ± 2° C 75% ± 5% RH for 36 Months.

Batch No.	Mfg. Date
CBPI00518C	Sep. 2018
CBPI00618C	Sep. 2018
CBPI00718C	Sep. 2018

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

i. The Firm has submitted **Scanned Copy** of legalized & notarized CoPP Certificate No. 4429584/TS/2023 dated 08-08-2023 issued by Drugs Control Administration, Telangana State for Carboplatin Concentrate for Solution for Infusion BP 450mg/45ml (CARBO SPAL-L 450), valid up to 05/10/2025. **Please provide Original legalized & notarized document for the same.**

ii. Finished product specifications have been claimed as "BP" whereas in section 3.2.P.2.1 Specifications No. FPIN018-S-02, Effective 30-04-2021, Reference for Identification, Assay and Related Substances by HPLC has been claimed as "In-House". Please justify.

iii. Firm has submitted **Photocopy** of notarized 'Authorization Letter' issued by M/s SP Accure Labs Private Limited. **Please provide Original notarized document for the same.**

iv. **"Annex 1"** claimed to be enclosed with above 'Authorization Letter' has not been submitted in application dossier.

v. The name of firm as mentioned on 'Authorization Letter' and information provided by FPP Manufacturer throughout the application dossier states its name as "**M/s SP Accure Labs Private Limited".** However, the name of FPP Manufacturer as evident from documents issued by Regulatory Authority of country of origin specifies it as **M/s SPAL Private Limited.** Please justify / provide supporting documents for change of name to 'M/s SP Accure Labs Private Limited' issued by concerned authorities.

vi. The label claim has been mentioned throughout the application dossier as "Each **ml Vial** contains…", whereas the proposed pack size is **45ml Vial**. Please justify.

Decision: Deferred for submission of reply to above cited shortcomings.

Agenda of Evaluator PEC-XXI

22.	Name, address of Applicant / Importer	**M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi.**
	Details of Drug Sale License of importer	DSL No. DHODSK(Drugs)/-809. Status: Drug License by way of whole sale. Address: M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi. Valid up to 08-12-2027.
	Name and address of marketing authorization holder (abroad)	M/s Zydus Healthcare Limited. CTS No. 460/6, I.B. Patel Road, Village Pahadi, Goregaon East, Mumbai-400063, India.
	Name, address of manufacturer(s)	M/s SP Accure Labs Pvt. Ltd., Plot No. 12, Biotech Park, Phase II, Lalgadi Malakpet (V) Shamirpet (M), Medchal – Malkajgiri (Dist.), Telangana (State), India.
	Name of exporting country	India.

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Detail of certificates attached (CoPP, GMP certificate) • Colored copy of CoPP (certificate No. 3474593/TS/2022 dated 21-10-2022 issued by Drugs Control Administration Telangana for cisplatin concentrate for solution for infusion BP 50mg/50ml valid till 24-08-2025 is submitted. The document also confirms that the applied product strength is actually on the market in exporting country. However, as per COPP certificate the product license holder is M/s SPAL Pvt. Ltd., India. • Copy of GMP certificate No. 82237/TS/2022 dated 03-03-2022 issued by Drugs Control Administration, Telangana in the name of M/s SPAL Private Limited valid till 02-03-2023 is submitted.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of sole distribution letter between M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi and M/s Zydus Healthcare Limited, located at Zydus corporate park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandinagar Highway, Ahmad Abad, India. Document has mentioned that M/s Zydus Healthcare Limited, is MAH. However, CoPP has mentioned M/s SPAL Pvt. Ltd., India as MAH for the product. Agreement has mentioned that M/s Wellociti upon registration of products in Pakistan shall be the sole authorized importer for the products (14) in Pakistan. Firm has also submitted copy of contract manufacturing agreement between M/s Zydus Healthcare Limited and M/s SP Accure Labs Pvt. Ltd., wherein M/s Zydus Healthcare Limited is engaged in sale marketing and distribution of wide range of pharmaceutical products in various countries. While M/s SP Accure Labs Pvt. Ltd., is engaged in manufacturing, sales and distribution of pharmaceutical products in India.
	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. 23761: dated 21-11-2023.
	Details of fee submitted	PKR 150,000/-: vide slip No. 7551511337 dated 07-08-2023.
	The proposed proprietary name / brand name	**Cisplat 50.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml vial contains: Cisplatin..... 50mg.

	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion.
	Pharmacotherapeutic Group of (API)	Other Antineoplastic Agents, Platinum compound.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1 vials in a carton along with pack insert.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Cisplatin 50mg/vial, USFDA approved.
	For generic drugs (me-too status)	Cipintu concentrated solution for infusion, Himmel pharma, Reg. No. 099486.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, 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. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacturer, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Sun pharmaceutical Industries Limited, A-7/A-8, M.I.D.C., Industrial Area, Ahmednagar – Maharashtra, India. Copy of GMP certificate No. NEW-WHO-GMP/CERT/NKD/72512/2018/11/24746 dated 30-08-2018 issued by Food & Drugs Administration M.S. Bandra - Mumbai valid till 29-08-2021 is submitted.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 72 months' real time stability data at 25°± 2°C / 60% RH ± 5% RH of 03 batches (AH-3-08013, AH-3-08014 & AH-3-08015). • 06 month accelerated stability data 40°C ± 2°C / 75% RH ± 5% RH of 03 batches (AH-3-08013, AH-3-08014 & AH-3-08015).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against product i.e. Cisplatin NeoCorp 1mg/ml, Lot No. JG5128 MAH Hexal AG Industries by performing the following tests; Description, Identification, pH, Assay & Related substances.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	10ml amber 20mm collar vials (flat bottoms) with 20mm 4432/50 gray fluorotec B2 coating westarrs serum stopper and sealed with 20mm easy to open C/L Alu. Seals with matt finish plastic purple.
	Stability study data of drug product, shelf life and storage conditions	• 36-month real time stability data at 30°C ± 2°C / 75% ± 5% RH of 03 batches (CISI00118C (I), CISI00118C (U) & CISI00218C (I)). • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5% RH of 03 batches (CISI00118C (I), CISI00118C (U) & CISI00218C (I)).

Evaluation by PEC:

Sr. No.	**Section**	Observations	Reply by the firm.
1.	•	• Notarized agreement shall be submitted. • Address of the marketing authorization holder mentioned in 1.4 and that mentioned in sole distribution agreement are different. Clarification shall be submitted.	
2.		Valid, notarized and legalized copy of GMP certificate of the manufacturer shall be submitted.	
3.	•	• Notarized and legalized copy of CoPP certificate shall be submitted. • Submitted CoPP has mentioned M/s SPAL Pvt. Ltd., India as product license holder while the agreement of the M/s Wellociti is with M/s Zydus Healthcare Limited. Clarification shall be submitted.	
4.	1.4.1	Section 1.4.1 has mentioned domestic and export sales while the sole distribution agreement has mentioned in Pakistan only. Clarification shall be submitted.	
5.	3.2.S.4.2	BP monograph has mentioned injection volume of 20µl while the specifications submitted by both the drug substance and drug product manufacturer has mentioned 10µl. clarification shall be submitted.	
6.	3.2.P.1	Qualitative composition of the applied formulation is different from innovator with respect to mannitol. Clarification shall be submitted.	
7.	3.2.P.2.2	Justification shall be submitted for not performing uniformity of content, sterility and bacterial endotoxin test in PE studies.	

Decision: Deferred for submission of reply to above cited shortcomings.

Import & Vet-II Section

Case 1. Registration of drug under DRAP Act 2012

Registration Board in 312th meeting considered & approved the following product of M/s Lab Diagnostic Systems (SMC) Pvt Ltd, Taxila Rawalpindi as per following details:

Name of Importer/Manufacturer	Product Name & Composition	Decision
M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 111B, Hali Road, Westridge 1, Rawalpindi Cantt., Pakistan **Manufacturer & Product License Holder:** M/s Jiangsu Hengrui Pharmaceuticals Co., Ltd. No. 38, Huanghe road, Economic and technological Development Zone, Lianyungang	Ethiodized Poppyseed Oil Injection Each vial contains: Ethiodized Poppyseed Oil Injection 10**ml** (contains Iodine 480mg/ml)	Approved with innovator's specifications as per import policy for inspection of Manufacturer abroad and verification of local storage facility for shelf life of 6months with storage condition below 30 °C

ii. As the product contains Ethiodized Poppyseed Oil Injection, the case was forwarded to the Controlled Drugs Division for their opinion on whether the NOC (No Objection Certificate) from the Ministry of Narcotics Control is required or not.

iii. The Controlled Drugs Division attached a letter from the Ministry of Narcotics Control, which states that "all parts of the poppy plant are restricted except for its seeds. However, any preparations containing more than 0.2% of Morphine or Diacetylmorphine are prohibited."

iv. The importer was asked to submit a reply in light of the letter from the Ministry of Narcotics Control.

v. Now, they have submitted a letter from the manufacturer abroad, which shows that their product does not contain Morphine or Diacetylmorphine.

Decision of 333rd meeting: The Board endorsed the decision of approval granted in 312th meeting of Registration Board for the following product formulation keeping in view the comments from Division of Controlled Drug, DRAP and reply of the firm.

Ethiodized Poppyseed Oil Injection
Each vial contains:
Ethiodized Poppyseed Oil Injection 10ml (contains Iodine 480mg/ml)

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s Mallard Pharmaceuticals (Pvt.) Ltd., 23-Km, Lahore Road, Multan, 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.	Copy of DML provided Approval of relevant section verified from letter No. F 1-14/2004-Lic (Vol-II) dated26-10-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 13-08-2020
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. 1255/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.	Omnirox Injection Each 1 ml contains: Naproxen Sodium 50mg	Export Order Required.	Dy. No. 1485/22 (19.12.2023) Rs.30,000/- (21.11.2023) Rs.45,000/- (15.12.2023)

Decision: Registration Board deliberated that although the aforementioned formulation is neither me too formulation nor available in any RRA. However, the said formulation does not require special manufacturing conditions. Hence, to increase the export revenue of the country, Registration Board approved above product exclusively for export purpose only.

Agenda for the procedure for capacity assessment of the contract accepter

1. Inspection of contract accepter for manufacturing / testing capacity assessment shall be conducted for all those contract manufacturers, who has not been inspected for such purpose with in the last 3 years. The panel shall verify capacity assessment of all those sections, which are approved by the Licensing Division.

2. Capacity assessment of newly applied facility (Section) shall not be carried out, if any section of that manufacturing facility has already been assessed within last three years.

3. Following shall be prerequisites for submission of application for contract manufacturing under Rule 20 (A) of Contract Manufacturing Policy.

    a. Affidavit on stamp paper (Showing name, designation, CNIC Number of contract giver) stating installed capacity of the contract accepter for contract manufacturing. This affidavit shall only be signed by the CEO / MD of the firm. i.e. contract accepter.
    b. Copy of DML of both firms. i.e. contract giver and contract accepter along with Section (s) approval from Licensing Division.
    c. Valid GMP certificate or GMP inspection report of the contract accepter, conducted within last three years.
    d. Copy of legalized contract between contract giver and contract accepter on stamp paper presenting the capacities of the contract accepter for the manufacturing sections for whom the products have been applied, and

4. Affidavits submitted by the contract accepter, showing manufacturing / testing capacity, will be verified in the subsequent inspections conducted for GMP / renewal of DML and will be reported accordingly. Chairman, Registration Board may constitute panel of experts to verify capacity assessment, if required.
5. The capacity verification report will be valid for 3 years.

Agenda regarding the submission of duplicate dossiers of Form 5

The Registration Board discussed the submission of duplicate dossiers (Duplicate copy of already submitted dossier with requisite fee and duly verified by the DRAP) on Form-5 or Form-5D with complete stability study data submitted in PE&R Division till 31st December, 2023.

The Board after thorough deliberations recommended that said duplicate dossiers may be submitted till 31st March, 2024 for consideration of Registration Board. The Board also directed PEC Section to issue a circular to PPMA and Pharma Bureau for compliance of aforesaid decision by the relevant applicants after approval from the authority.

The PE&R division was also directed to forward the agenda/recommendation of the board for the approval of Authority without waiting the finalization of minutes.

The Board recommended the above for the approval of Authority, please.

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